Supreme Court, U.S.
FILED

No. 06-___ 061016 JAN 22 2007

OFFICE OF THE CLERK

In The

Supreme Court of the United States

RANBAXY LABORATORIES LIMITED AND
RANBAXY PHARMACEUTICALS INC.,

Petitioners,

—against—

PFIZER INC., PFIZER IRELAND PHARMACEUTICALS,
WARNER-LAMBERT COMPANY,
WARNER-LAMBERT COMPANY, LLC, AND
WARNER-LAMBERT EXPORT, LTD.,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

WILLIAM R. ZIMMERMAN
Counsel of Record
DARRELL L. OLSON
JOSEPH M. REISMAN
PAYSON LEMEILLEUR
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main Street, 14th Floor
Irvine, California 92614
(949) 760-0404

January 22, 2007

Attorneys for Petitioners

COCKLE LAW BRIEF PRINTING CO. (800) 225-6964
OR CALL COLLECT (402) 342-2831

QUESTION PRESENTED

Whether the Federal Circuit erred by failing to apply the statute and regulation mandating disclosure of all material information to the Patent Office by a pharmaceutical company seeking a patent term extension and, instead, adopting a *per se* rule under which a pharmaceutical company need not disclose certain information, including prior inconsistent statements made to the Patent Office, regarding the breadth and disclosure of the very patent for which a term extension is sought.

CORPORATE DISCLOSURE STATEMENT

No publicly held company owns 10% or more of the stock of Petitioner Ranbaxy Laboratories Limited. Petitioner Ranbaxy Pharmaceuticals Inc. is a wholly-owned subsidiary of Ranbaxy [Holdings] UK Ltd., which is a wholly-owned subsidiary of Ranbaxy Netherlands B.V., which is a wholly-owned subsidiary of Ranbaxy Laboratories Limited.

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
CORPORATE DISCLOSURE STATEMENT	ii
OPINIONS BELOW	1
JURISDICTION	1
STATUTORY PROVISIONS INVOLVED	2
STATEMENT OF THE CASE	2
I. The Technology At Issue	7
II. Pfizer's Development Of, And Patent Protection For, Lipitor	7
A. The '893 Patent	7
B. The '995 Patent	8
C. The '893 Patent Term Extension	10
III. Ranbaxy's Generic Product	11
IV. The Proceedings Below	12
A. The District Court's Decision	12
B. The Federal Circuit's Decision	14
REASONS FOR GRANTING THE PETITION	15
I. The Federal Circuit's *Per Se* Rule Is Contrary To Statute	15
II. The Federal Circuit's *Per Se* Rule Is Contrary To Precedent	20
III. This Case Presents A Good Vehicle For Resolving The Important Question Presented	26
CONCLUSION	30

TABLE OF AUTHORITIES

Page

FEDERAL CASES

Abbott Labs. v. Dey, L.P., 287 F.3d 1097 (Fed. Cir. 2002) 13, 14, 23, 24

Chevron, U.S.A., Inc. v. Natural Res. Def Counsel, Inc., 467 U.S. 837 (1984) 20

In re Dubno, 12 U.S.P.Q.2d 1153 (Comm'r Patents & Trademarks June 30, 1989) 16

Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661 (1990) 3

Glaxo, Inc. v. Novopharm Ltd., 110 F.3d 1562 (Fed. Cir. 1997) 3

Goldenberg v. Cytogen, Inc., 373 F.3d 1158 (Fed. Cir. 2004) 14, 23

Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860 (Fed. Cir. 2003), *vacated on other grounds*, 545 U.S. 193 (2005) 13, 23

KSR Int'l Co. v. Teleflex Inc., 126 S. Ct. 2965 (2006) ... 24, 25

Laitram Corp. v. Cambridge Wire Cloth Co., 863 F.2d 885 (Fed. Cir. 1988) 13

Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996) 22

Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996) 21

Nobelpharma AB v. Implant Innovations, Inc., 129 F.3d 1463 (Fed. Cir. 1997) 25

Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059 (Fed. Cir. 1998) 26

TABLE OF AUTHORITIES – Continued

Page

Norton v. Curtiss, 433 F.2d 779 (C.C.P.A. 1970) 4

Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*) 22

Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806 (1945) 4

Purdue Pharma L.P. v. Endo Pharms. Inc., 410 F.3d 690 (Fed. Cir. 2005) 25

Purdue Pharma L.P. v. Endo Pharms. Inc., 438 F.3d 1123 (Fed. Cir. 2006) 25

Texas Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193 (Fed. Cir. 2002) 23

Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172 (1965) 25

FEDERAL STATUTES

21 U.S.C. § 355 11

28 U.S.C. § 1254 1

28 U.S.C. § 1295 1

28 U.S.C. § 1338 ..... 1, 12

35 U.S.C. § 3 4

35 U.S.C. § 120 6

35 U.S.C. § 156 ..... *passim*

35 U.S.C. § 271 12

35 U.S.C. § 282 ..... 2, 6, 19

37 C.F.R. § 1.765 ..... *passim*

TABLE OF AUTHORITIES – Continued

Page

OTHER AUTHORITIES

Rules for Extension of Patent Term, 51 Fed. Reg. 27,205 (July 30, 1986) 15

Rules for Extension of Patent Term, 52 Fed. Reg. 9,386 (Mar. 24, 1987) 15, 16

Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. 98-417, 98 Stat. 1585 3

Generic Drug Entry Prior to Patent Expiration; An F.T.C. Study (2002) 28

Prepared Statement of the Federal Trade Commission before the Special Committee on Aging of the United States Senate of Barriers to Generic Entry, July 20, 2006 28

PETITION FOR A WRIT OF CERTIORARI

Ranbaxy Laboratories Limited and Ranbaxy Pharmaceuticals Inc. (collectively, "Ranbaxy") hereby petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit entered in this action on August 2, 2006.

OPINIONS BELOW

The opinion of the Court of Appeals is reported at 457 F.3d 1284 and appears in the Appendix ("App.") at 1-16. The order of the Court of Appeals denying panel rehearing and rehearing *en banc* is unreported and appears at App. 80-81. The memorandum opinion of the United States District Court for the District of Delaware is reported at 405 F. Supp. 2d 495 and appears at App. 17-72. The final judgment of the District Court is unreported and appears at App. 73-75. The District Court's first and second modifications to its final judgment are unreported and appear at App. 76-77 and App. 78-79, respectively.

JURISDICTION

The judgment of the Court of Appeals was entered on August 2, 2006. A petition for panel rehearing and rehearing *en banc* was filed August 15, 2006. The Court of Appeals denied the petition on October 23, 2006, and issued the mandate on October 30, 2006. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

The District Court had jurisdiction to hear Respondent's claims for alleged patent infringement under 28 U.S.C. § 1338(a). The Federal Circuit had jurisdiction to hear Petitioner's appeal under 28 U.S.C. § 1295(a)(1).

STATUTORY PROVISIONS INVOLVED

The relevant statutory provisions, 35 U.S.C. §§ 156, 282, and regulation, 37 C.F.R. § 1.765, concerning the disclosure required from an applicant for a patent term extension are set out at App. 83-105.

STATEMENT OF THE CASE

This case presents an important federal question: In seeking a patent term extension under 35 U.S.C. § 156 on the basis that the patent claims an approved drug, do the controlling statute and regulation require a pharmaceutical company to disclose (1) its own prior, inconsistent representations made before the United States Patent and Trademark Office ("Patent Office") that the patent does not cover the approved drug, (2) a Patent Office Board of Patent Appeals and Interferences ("Board") decision adopting those representations, and (3) a later patent claiming the drug on which the patent term extension application is premised, or is this information *per se* irrelevant to the patent term extension proceedings?

This case arises in the specific context of Pfizer's[1] strategy to prevent generic competition to the world's most widely-prescribed and best-selling drug, Lipitor®. Nonetheless, the issue presented has far-reaching implications. Indeed, the issue presented impacts nearly every American because it determines the length of effective patent protection for numerous prescription drugs and, thus, determines when lower-cost generic alternatives are made

[1] For ease of reference, this petition uses "Pfizer" to refer to the various Pfizer and Warner-Lambert entities both individually and collectively. The distinction between these entities is immaterial to the issue presented.

available. In this case, if Pfizer failed to comply with its duty of disclosure to the Patent Office, its patent term extension is invalid. Thus, resolution of the question presented will literally determine whether consumers, the federal government, and state governments will continue to pay billions of dollars over the next three years to obtain Lipitor, or whether a lower-cost generic alternative may be marketed during that time.

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. 98-417, 98 Stat. 1585 (hereinafter "the Hatch-Waxman Act"), "legislation designed to benefit makers of generic drugs, research-based pharmaceutical companies, and not incidentally the public." *Glaxo, Inc. v. Novopharm Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997). One of the central purposes of this legislation was to make an increased number of generic drugs available more cheaply and quickly, benefiting both generic drug manufacturers and the public. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990) (explaining that the statutory provisions governing abbreviated new drug applications would "enable new drugs to be marketed more cheaply and quickly"); *Glaxo*, 110 F.3d at 1568.

The Hatch-Waxman Act also "established a patent-term extension for patents relating to certain products that were subject to lengthy regulatory delays and could not be marketed prior to regulatory approval." *Eli Lilly*, 496 U.S. at 670. These patent term extensions were designed to allow research-based pharmaceutical companies to recoup some of the patent term effectively lost while awaiting regulatory approval for their drugs. The statutory provisions governing these patent term extensions were codified at 35 U.S.C. § 156.

In any proceeding before the Patent Office, disclosure of relevant information by the applicant is of paramount importance because the applicant is generally aware of information otherwise unavailable to the Patent Office. *See Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945); *Norton v. Curtiss*, 433 F.2d 779, 793-94 (C.C.P.A. 1970). Congress expressly delegated to the Patent Office the authority to adopt regulations setting the substantive disclosure requirements for an applicant for patent term extension. 35 U.S.C. § 156(d)(4) ("An application for the extension of the term of a patent is subject to the disclosure requirements prescribed by the Director.").[2]

Pursuant to this authority, the Patent Office promulgated 37 C.F.R. § 1.765, which defines the duty of disclosure required by an applicant. This regulation provides that anyone "substantively involved on behalf of the patent owner in a patent term extension proceeding" owes "[a] duty of candor and good faith toward the Patent and Trademark Office." 37 C.F.R. § 1.765(a). The regulation further provides:

> All such individuals who are aware, or become aware, of material information adverse to a determination of entitlement to the extension sought, which has not been previously made of record in the patent term extension proceeding must bring such information to the attention of the Office. *Id.*

---

[2] The statutory reference to "Director" is to the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office. 35 U.S.C. § 3(a)(1).

The regulation defines material information as follows:

> Information is material where there is a substantial likelihood that the Office or the Secretary would consider it important in determinations to be made in the patent term extension proceeding. *Id.*

Thus, the Patent Office has adopted broad disclosure requirements, mandating disclosure of all information that is substantially likely to be important in the extension proceeding – without any limitation as to the context in which the information arises.

In a patent term extension proceeding, this duty of candor by the applicant takes on heightened importance because the Patent Office may grant the patent term extension "solely on the basis of the representations contained in the application for the extension."[3] 35 U.S.C. § 156(e)(1). The Patent Office can enforce the duty to disclose material information; it will not issue a patent term extension if it determines that "the duty of disclosure was violated through bad faith or gross negligence in connection with the patent term extension proceeding." 37 C.F.R. § 1.765(c). The failure of an applicant to comply with the duty to disclose material information will render the patent term extension invalid and is a defense to

[3] In a patent term extension proceeding, the Patent Office does not independently search for information relevant to the term extension proceeding, but instead relies on the information submitted by the applicant in the application. Thus, in assessing a patent term extension application, the Patent Office does not have before it information that may have arisen in Patent Office proceedings other than during prosecution of the application sought to be extended. Accordingly, the Patent Office relies on the applicant to disclose any such material information.

alleged infringement of the patent term extension. 35 U.S.C. § 282, ¶ 4.

The Federal Circuit refused to apply the Patent Office's regulations, promulgated pursuant to the authority delegated by Congress. Instead, the Federal Circuit adopted a much more narrow standard of disclosure. The Federal Circuit held that an applicant's own representations to the Patent Office regarding its patent are *per se* irrelevant, and thus not material to the term extension proceedings, provided that those representations were made during prosecution of a later, formally-unrelated patent application.[4] The Federal Circuit took the same *per se* view with respect to a Board decision adopting the patentee's representations, as well as a later-issued, formally-unrelated patent specifically disclosing and claiming the drug upon which the patent term extension application is premised.

The Federal Circuit's *per se* rule thwarts the Patent Office's disclosure regulations and is contrary to 35 U.S.C. § 156(d)(4), which expressly authorizes the Patent Office to prescribe the disclosure required from a patent term extension applicant. The Federal Circuit's refusal to enforce the Patent Office's disclosure regulations usurps the Patent Office's authority. The issue of whether a patent term extension applicant must disclose its prior inconsistent statements to the Patent Office, as well as

[4] In this context, whether two patents are "formally related" refers to the technical issue of whether one patent claims priority to the other or whether the patents claim priority to a common patent or application. Patents that share such a relationship are "formally related" in the technical sense of their priority claim, while patents that do not share such a relationship are "formally unrelated." *See* 35 U.S.C. § 120.

other information, is ripe for review by this Court, and this case presents a good vehicle for such review.

I. The Technology At Issue

This case involves Lipitor, a drug used to treat high cholesterol. This condition afflicts many millions of people, increasing their risk of heart attack and stroke. Lipitor is currently prescribed to over eight million Americans and is the world's most widely prescribed drug. It is the largest selling drug in history and was the first drug to have annual global sales of over $10 billion. In 2005, global sales of Lipitor exceeded $12 billion.

The active ingredient in Lipitor is atorvastatin calcium, which is an enantiomer. An enantiomer is an isomer that has a mirror-image isomer, like a human right hand mirrors a human left hand. An enantiomer and its opposite enantiomer have the same atomic composition, but a different spatial arrangement of atoms.[5] Racemates comprise equal amounts of two opposite enantiomers. However, racemates are distinct from their constituent enantiomers, generally having different physical properties than either constituent enantiomer.

II. Pfizer's Development Of, And Patent Protection For, Lipitor

A. The '893 Patent

In the mid-1980's, chemists at Pfizer made and tested several racemate drug candidates as part of their work to

[5] Each enantiomer of the pair is a distinct isomer often having unique physical and medicinal properties. For example, one enantiomer of thalidomide is effective against morning sickness while the other enantiomer causes birth defects.

develop a drug to treat high cholesterol. At this time, Pfizer had not made any enantiomers as part of this development work.

On May 30, 1986, Pfizer filed a first patent application in an effort to protect the drugs it had then developed. This application issued as U.S. Patent No. 4,681,893 ("the '893 patent") on July 21, 1987, and its natural, unextended term expired on May 30, 2006. Pfizer alleges in this action that this patent covers a broad class of compounds that includes the enantiomer in Lipitor, atorvastatin calcium.

B. The '995 Patent

In 1987, the Food and Drug Administration ("FDA") issued new guidelines favoring the use of enantiomers over racemates as drugs. In view of these guidelines, Pfizer made the enantiomer atorvastatin calcium for the first time and shifted its focus to commercially developing this enantiomer.[6]

With the '893 patent, allegedly broadly covering Lipitor, already in hand, Pfizer sought to extend its patent protection over Lipitor by filing a second, follow-on patent application that specifically disclosed and narrowly sought to claim the enantiomer atorvastatin calcium. This second application and Pfizer's earlier '893 patent have the same inventor, the same assignee, and disclose and claim similar subject matter. However, because the '893 patent had already issued at the time this second application was filed, no claim of priority to the '893 patent could be made.

---

[6] Pfizer first produced the enantiomer atorvastatin calcium using resolution, a well-known chemical process in which a racemate containing equal amounts of two opposite enantiomers is separated into its component enantiomers.

Thus, this second application and the '893 patent are formally unrelated. Rather, the '893 patent is prior art to this second application.

The Patent Office repeatedly rejected Pfizer's follow-on patent application, deeming its claims to enantiomers to be anticipated by Pfizer's earlier '893 patent. To overcome the Patent Office's rejections of this second patent application, Pfizer attempted to distinguish the application's claims to enantiomers from Pfizer's earlier '893 patent. Pfizer repeatedly represented to the Patent Office that the '893 patent is limited to racemates and does not disclose, teach, or enable enantiomers. Specifically, Pfizer represented:

- The presently claimed compounds [of the '995 patent] are for individual enantiomers and therefore differ from the teaching in [the '893 patent] only to mixtures of enantiomers [i.e., racemates].
- [E]ach isomer of [the '893 patent] is a mixture of enantiomers and not the currently claimed individual enantiomers. . . .
- [The '893 patent's] disclosure [is] limited to a mixture of enantiomers.
- The mere suggestion of isomers in the Roth patent, U.S. 4,681,893, is not enabling and therefore is not anticipatory.
- [N]owhere does [the '893 patent] suggest or teach how one can prepare, isolate or separate the mixtures to prepare or isolate the desired R isomer [i.e., enantiomer] free from the corresponding S isomer.
- The present invention is directed to a novel optical isomer which was not made and not known to have the properties it has at the time of the Roth

> patent, U.S. 4,681,893. Furthermore, the description in Roth is not such that one skilled in the art would have been possessed of the isomer at that time.

After appeal proceedings, the Board ultimately adopted Pfizer's representations that the '893 patent only describes racemates and does not describe enantiomers, including the enantiomer in Lipitor, atorvastatin calcium:

> [The '893 patent], at best, only describes the trans racemate containing the R-trans and S-trans isomers in admixture. Nowhere does Roth state or suggest which optical isomer is preferred and, moreover, does not specifically mention how one skilled in the art could make the pure optical isomer separately.

Consequently, on December 28, 1993, Pfizer obtained U.S. Patent No. 5,273,995 ("the '995 patent"), which specifically discloses and claims the enantiomer atorvastatin calcium.[7]

C. The '893 Patent Term Extension

After Lipitor received FDA approval, Pfizer explored whether it could extend its patent protection still further through a patent term extension. However, the '995 patent was not eligible for a patent term extension under the applicable statute because its remaining term was too long to be further extended. 35 U.S.C. § 156(c)(3). Therefore, on February 7, 1997, Pfizer instead filed an application with the Patent Office to extend the term of the '893 patent pursuant to 35 U.S.C. § 156. In this application, Pfizer represented that the '893 patent claims the enantiomer

---

[7] The Federal Circuit has determined that the specific claim of the '995 patent directed to atorvastatin calcium, Claim 6, is invalid.

atorvastatin calcium, i.e., Lipitor, despite Pfizer's repeated earlier representations to the Patent Office that the '893 patent does not disclose, teach, or enable any enantiomers, such as atorvastatin calcium.

Importantly, despite acknowledging the duty to disclose material information, Pfizer withheld from the Patent Office (1) Pfizer's repeated, prior representations that the '893 patent does not disclose, teach, or enable enantiomers, (2) the Board's decision adopting Pfizer's representations, and (3) the very existence of the '995 patent, which specifically discloses and claims the enantiomer atorvastatin calcium.[8] Not having been made aware of this material information by Pfizer in the patent term extension application, the Patent Office granted the patent term extension and thereby extended the term of the '893 patent by more than three years – to September 24, 2009.

III. Ranbaxy's Generic Product

On August 19, 2002, Ranbaxy filed an Abbreviated New Drug Application ("ANDA") pursuant to 21 U.S.C. § 355(j) seeking FDA approval to market a generic version of Lipitor. Ranbaxy's ANDA sought permission to market its generic alternative prior to expiration of the extended '893 patent and the '995 patent.

---

[8] It is undisputed that the attorney who filed and prosecuted the application for patent term extension was aware of all of this information, but chose not to submit it in connection with the patent term extension.

IV. The Proceedings Below

Seeking to prevent generic competition, Pfizer filed suit against Ranbaxy in the District Court, alleging that Ranbaxy's ANDA product would infringe the '893 and '995 patents under 35 U.S.C. § 271(e)(2)(A). The District Court had jurisdiction over Pfizer's infringement claims pursuant to 28 U.S.C. § 1338(a). Ranbaxy raised affirmative defenses and counterclaims alleging noninfringement, that the patents were invalid and/or unenforceable, and that the '893 patent term extension was invalid.

A. The District Court's Decision

Following a bench trial, the District Court found that the '893 and '995 patents were not invalid or unenforceable and that Ranbaxy's ANDA product would infringe both patents. The District Court entered final judgment and an injunction against Ranbaxy on January 4, 2006.[9]

With respect to the '893 patent term extension, the District Court ruled that the information withheld by Pfizer was not material, going so far as to characterize this information as "irrelevant." In reaching this conclusion, the District Court did not analyze whether Pfizer's representations and the Board's decision regarding the '893 patent were material under the controlling regulation, 37 C.F.R. § 1.765(a). The District Court also did not analyze

---

[9] The unextended term of the '893 patent is no longer at issue because it expired on May 30, 2006. The '995 patent is also no longer at issue because the Federal Circuit has ruled that Claim 6, the only claim asserted against Ranbaxy, is invalid. Accordingly, the validity of the '893 patent term extension is the only impediment to Ranbaxy marketing its generic alternative to Lipitor and the only issue presented in this petition.

whether Pfizer's later '995 patent was material under the regulation. Indeed, the District Court did not analyze the substance of this information at all in upholding the validity of the patent term extension.

Instead, in the context of construing the claims of the '893 patent, the District Court determined that Pfizer's representations and the Board's decision adopting those representations were *per se* irrelevant, stating:

> [T]he Federal Circuit has repeatedly held that arguments from a later, unrelated patent prosecution cannot be used to interpret and/or limit an earlier, unrelated and already issued patent.[10]

Based on its claim construction analysis, the District Court held that the information at issue was not material to the patent term extension proceedings.

Thus, the District Court replaced the proper analysis of whether the information withheld by Pfizer was material under the standard set forth in the Patent Office regulations with a *per se* rule from the Federal Circuit's claim construction precedent. In so doing, the District Court provided no analysis or reasoning to support its decision to substitute this *per se* rule for the fact-based analysis of materiality prescribed by the Patent Office regulation and the governing statute.[11]

---

[10] The District Court cited *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 868 (Fed. Cir. 2003), *vacated on other grounds*, 545 U.S. 193 (2005); *Abbott Labs. v. Dey, L.P.*, 287 F.3d 1097, 1099-1100, 1104-05 (Fed. Cir. 2002); and *Laitram Corp. v. Cambridge Wire Cloth Co.*, 863 F.2d 885, 862 n.16 (Fed. Cir. 1988) in support of its conclusion. None of these cases address the disclosure required by an applicant for a patent term extension.

[11] In 2005 and 2006, the District Court and the Federal Circuit, respectively, held that the '893 patent claims enantiomers, including the enantiomer in Lipitor, atorvastatin calcium. These rulings ultimately

(Continued on following page)

B. The Federal Circuit's Decision

The Federal Circuit's opinion provided no substantive analysis of the validity of the '893 patent term extension. Rather, in a mere two sentences, the Court concluded that there was no clear error in the District Court's determination that the information withheld by Pfizer was irrelevant.

In endorsing the District Court's analysis, the Federal Circuit has condoned replacing the materiality standard adopted by the Patent Office for patent term extension proceedings with a more narrow, *per se* rule lifted from a branch of the Federal Circuit's claim construction jurisprudence.[12] Under this standard, a patentee's representations to the Patent Office and the Board's decision accepting those representations are *per se* irrelevant to a patent term extension proceeding if they occurred during the prosecution of a formally-unrelated patent application.

---

mean that the representations Pfizer made to the Patent Office regarding the '893 patent during prosecution of the '995 patent were incorrect. Nonetheless, these rulings have no impact on the materiality of Pfizer's representations to the Patent Office for purposes of the 1997-98 patent term extension proceedings. Accordingly, these rulings are irrelevant to the validity of the patent term extension, the sole issue presented in this petition.

[12] In construing the claims of the '893 patent, the Federal Circuit, like the District Court, determined that "statements made during prosecution of the later, unrelated '995 patent cannot be used to interpret claims of the '893 patent," citing *Goldenberg v. Cytogen, Inc.*, 373 F.3d 1158, 1167-68 (Fed. Cir. 2004) and *Abbott*, 287 F.3d at 1104-05.

REASONS FOR GRANTING THE PETITION

I. The Federal Circuit's *Per Se* Rule Is Contrary To Statute

Congress expressly delegated to the Patent Office the authority to prescribe the disclosure requirements in connection with a patent term extension application. 35 U.S.C. § 156(d)(4). The Patent Office properly exercised this delegated authority by seeking notice and comment on proposed regulations, and thereafter adopting final regulations controlling the duty of disclosure by a patent term extension applicant. *Rules for Extension of Patent Term*, 51 Fed. Reg. 27,205, 27,208, 27,212 (proposed July 30, 1986); *Rules for Extension of Patent Term*, 52 Fed. Reg. 9,386, 9,391-92, 9,396-97 (Mar. 24, 1987) (to be codified at 37 C.F.R. pt. 1).

The applicable regulation imposes a duty of candor and good faith on every individual substantively involved in a patent term extension proceeding:

> A duty of candor and good faith toward the Patent and Trademark Office and the Secretary of Health and Human Services or the Secretary of Agriculture rests on the patent owner or its agent, on each attorney or agent who represents the patent owner and on every other individual who is substantively involved on behalf of the patent owner in a patent term extension proceeding. 37 C.F.R. § 1.765(a).

The regulation also specifies the disclosure required from these individuals:

> All such individuals who are aware, or become aware, of material information adverse to a determination of entitlement to the extension sought, which has not been previously made of record in the patent term extension proceeding

> must bring such information to the attention of the Office or the Secretary, as appropriate, in accordance with paragraph (b) of this section, as soon as it is practical to do so after the individual becomes aware of the information. Information is material where there is a substantial likelihood that the Office or the Secretary would consider it important in determinations to be made in the patent term extension proceeding. *Id.*

This duty of disclosure is paramount in a patent term extension proceeding because the Patent Office may grant the extension based solely on the representations contained in the application. 35 U.S.C. § 156(e)(1). Moreover, patent term extension proceedings are conducted *ex parte* between the applicant and the Patent Office, and the Patent Office will not consider submissions from third parties. 37 C.F.R. § 1.765(d); *Rules for Extension of Patent Term*, 52 Fed. Reg. 9,386, 9,392 (Mar. 24, 1987) (explaining the rationale for *ex parte* proceedings); *see In re Dubno*, 12 U.S.P.Q.2d 1153, 1154-55 (Comm'r Patents & Trademarks June 30, 1989) (rejecting a submission by an interested third party because patent term extension proceedings are conducted *ex parte*).

The Patent Office's disclosure regulations take a broad view of the information that an applicant must disclose, requiring submission of "material information adverse to a determination of entitlement to the extension sought." 37 C.F.R. § 1.765(a). Moreover, the regulations take a flexible approach as to what constitutes "material information" by specifying that such information need only be substantially likely to be important to the proceedings. Outside of these broad, flexible standards, the regulations do not deem any type of information to be *per se* irrelevant.

While the Federal Circuit paid lip-service to the Patent Office disclosure regulations, it failed to apply the governing standard. Instead, the Federal Circuit adopted a *per se* rule that the following information is legally irrelevant to a term extension proceeding: (1) representations made by the patentee to the Patent Office in prosecuting a second patent that the earlier patent sought to be extended does not disclose, teach, or enable the drug on which the application for extension is premised, (2) a decision by the Patent Office Board adopting the patentee's representations regarding the scope of the disclosure of the patent sought to be extended, (3) the existence of a subsequently-issued, follow-on patent that specifically claims the drug on which the extension application is premised. In excluding this information as *per se* "irrelevant," the Federal Circuit failed to provide any explanation as to how the controlling regulation supports this conclusion. No explanation was provided because the regulation cannot support this conclusion.

The Federal Circuit's *per se* rule excludes from disclosure information that is necessarily material under 37 C.F.R. § 1.765(a) and is subject to the Patent Office's duly promulgated disclosure regulation. In adopting its *per se* rule of exclusion, the Federal Circuit substituted its view of what information must be disclosed in a patent term extension proceeding for the standard in the regulation.

The Federal Circuit's *per se* rule not only undermines the rulemaking authority delegated to the Patent Office, but also deprives the Patent Office of the material information necessary to conduct proper patent term extension proceedings. The Federal Circuit's rule also effectively precludes any substantive review of an applicant's failure to disclose certain classes of information. The Federal

Circuit's new rule leads to serious and untenable consequences, as aptly demonstrated by the facts of this case.

During prosecution of the follow-on '995 patent, Pfizer repeatedly represented that its earlier '893 patent does not disclose, teach, or enable enantiomers, such as the enantiomer atorvastatin calcium found in Lipitor. Indeed, the Board issued a decision adopting Pfizer's position, paving the way for issuance of the later '995 patent.

In seeking to extend the term of the earlier '893 patent on the basis that this patent covers Lipitor, Pfizer never informed the Patent Office of (1) its representations regarding the '893 patent, (2) the Board's decision adopting Pfizer's representations, or (3) the existence of the '995 patent specifically disclosing and claiming Lipitor. Clearly, the Patent Office would have considered this information important in determining whether to extend the term of the '893 patent based upon the approval of Lipitor. Accordingly, this information is material under 37 C.F.R. § 1.765(a). This information, as with any public declaration by the applicant that the patent sought to be extended does not disclose, teach, or enable the relevant drug, is highly material and would have been important to the Patent Office in the patent term extension proceedings. However, by withholding this information, Pfizer denied the Patent Office any opportunity to consider this material information.[13]

Pursuant to statute, the failure to disclose material information is a defense in an infringement suit that will

---

[13] No one other than those substantively involved in the patent term extension proceedings on behalf of Pfizer could have brought these materials to the attention of the Patent Office. 37 C.F.R. § 1.765(a), (d) (precluding submission of information by third parties).

render the patent term extension invalid. 35 U.S.C. § 282, ¶ 4. Under a proper inquiry, a court would determine whether the withheld information was material by conducting a substantive analysis of whether that information satisfied the definition set forth in the controlling regulation, 37 C.F.R. § 1.765(a). In stark contrast, under the Federal Circuit's *per se* rule, no such analysis ever need be conducted. Accordingly, Pfizer escaped any judicial scrutiny as to whether the information it knowingly withheld from the Patent Office was material.

The rule endorsed by the Federal Circuit allows patentees to make flatly inconsistent representations to the Patent Office and the courts with impunity, as Pfizer has done here. The rule adopted by the Federal Circuit eliminates any substantive review, either by the Patent Office or by the courts, of a patentee's failure to submit certain types of information. This is neither what Congress nor the Patent Office intended in adopting the statutes and regulations governing disclosure in patent term extension proceedings.

Rather, the Patent Office has promulgated regulations governing disclosure pursuant to the authority delegated by statute. These regulations require disclosure of all information that is substantially likely to be important to the term extension proceedings. A patentee's representations regarding the scope of the patent in question and a Board decision adopting those representations clearly satisfy this standard. The Federal Circuit erred in failing to give effect to the Patent Office regulations and in instead adopting a *per se* rule excluding certain information from disclosure. Review is necessary to give proper effect to the Patent Office's disclosure regulations.

II. The Federal Circuit's *Per Se* Rule Is Contrary To Precedent

Under this Court's well-established precedent, an agency's proper legislative regulations are controlling. As explained in *Chevron, U.S.A., Inc. v. Natural Resources Defense Counsel, Inc.*, 467 U.S. 837, 843-44 (1984):

> The power of an administrative agency to administer a congressionally created . . . program necessarily requires the formulation of policy and the making of rules to fill any gap left, implicitly or explicitly, by Congress. If Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation. Such legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute. (quotations and citations omitted).

Here, Congress expressly delegated to the Patent Office the authority to prescribe regulations governing the disclosure required from an applicant for patent term extension. 35 U.S.C. § 156(d)(4). Instead of giving the Patent Office's regulation controlling weight, the Federal Circuit substituted its view of material information for the standard clearly set forth in the regulation, 37 C.F.R. § 1.765(a). Thus, the Federal Circuit's decision is contrary to well-established precedent.

In adopting a *per se* rule that certain information is "irrelevant," the Federal Circuit and the District Court did not rely on any statute, regulation, or precedent regarding patent term extension proceedings. Rather, both the Federal Circuit and the District Court premised their determinations on Federal Circuit precedent regarding

claim construction. Reliance on this precedent is misplaced for two reasons.

First, claim construction is a separate and distinct endeavor from assessing the validity of a patent term extension. Construing the claims of an issued patent is conducted by the judge in a suit for infringement. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388, 391 (1996). This inquiry is grounded in well-established precedent regarding how to construe written instruments, such as patents.

In contrast, assessing whether a patent term extension is invalid for failure to disclose material information is a judicial inquiry necessarily grounded in the statute and regulation governing what information is material in this context. In this inquiry, what qualifies as "material information" is limited only by the definition of that phrase in the controlling regulation, 37 C.F.R. § 1.765(a). Moreover, while one requirement of an application for patent term extension is that it must show that the patent sought to be extended claims the approved product, 35 U.S.C. § 156(d)(1)(B), the regulations in no way limit the information to be considered in the entirety of the patent term extension proceeding. The statute expressly states that the application must include "such patent or other information as the Director may require." 35 U.S.C. § 156(d)(1)(E). By regulation, the Patent Office requires disclosure of all material information as defined in the regulation. The regulation certainly does not exclude consideration of a patentee's public representations to the Patent Office, a Board decision adopting such representations, or the existence of a later patent claiming the drug on which the patent term extension application is premised, regardless of the context in which these materials

arose. The regulations, appropriately, do not shield public pronouncements made to the Patent Office, as does the Federal Circuit's rule. Thus, there is no basis for the Federal Circuit's decision to limit the scope of material information by reference to its own claim construction precedent.

Second, even if claim construction precedent were somehow relevant, which it is not, the precedent on which the Federal Circuit relied is ill-founded. Based on this Court's precedent, the *en banc* Federal Circuit has held that a court may consult evidence outside of the patent and its prosecution history in reaching its construction of the patent claims. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980-81 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996) (explaining that use of such extrinsic evidence is not improper and cataloging Supreme Court precedent in which such evidence was used in claim construction); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317-19 (Fed. Cir. 2005) (*en banc*). In its most recent pronouncement on this issue, the *en banc* Federal Circuit stated:

> Although we have emphasized the importance of intrinsic evidence in claim construction, we have also authorized district courts to rely on extrinsic evidence, which consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises. (quotations and citations omitted).

Phillips, 415 F.3d at 1317. Thus, neither this Court nor the *en banc* Federal Circuit have adopted *per se* rules regarding the use of extrinsic evidence. Indeed, both have adopted a flexible approach, which counsels using such

evidence to reach a claim construction that best fits with the patent and its prosecution history.

Despite this flexible approach to the use of extrinsic evidence, panels of the Federal Circuit have held that a patentee's representations to the Patent Office during prosecution of a later, formally-unrelated patent application cannot be used to construe the claims of an earlier-issued patent to the same patentee.[14] This rule categorically excluding courts from considering a patentee's own representations to the Patent Office regarding the scope of its issued patent is contrary to the controlling precedent of this Court and the Federal Circuit sitting *en banc*.[15]

Moreover, an analysis of the panel decisions adopting this rule shows that they are all premised on *Abbott Labs. v. Dey, L.P.*, 287 F.3d 1097, 1104-05 (Fed. Cir. 2002). In *Abbott*, a panel of the Federal Circuit determined that statements made by a patentee during prosecution of a later patent do not give rise to prosecution history estoppel, which limits the permissible range of equivalents for an earlier, unrelated patent. This unremarkable holding accords with precedent. The *Abbott* decision relates only to

---

[14] *Goldenberg*, 373 F.3d at 1166-68; *Integra*, 331 F.3d at 868-69; *Texas Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1211 (Fed. Cir. 2002).

[15] In this case, the Federal Circuit's decision that the information in question is *per se* irrelevant hinges on the fact that the information arose during prosecution of a formally-unrelated patent application before the Patent Office. This is truly ironic because if Pfizer had properly submitted the information in question to the Patent Office during the patent term extension proceedings, it would have been intrinsic evidence, i.e., part of the prosecution history of the patent term extension, and therefore properly considered under the Federal Circuit's precedent. It cannot be that whether this information can be analyzed for materiality turns on Pfizer's decision to withhold the information from the Patent Office in the first instance.

the doctrine of prosecution history estoppel, a legal limitation on the doctrine of equivalents and non-literal infringement. This decision is unrelated to claim construction and provides no basis for a *per se* rule limiting the types of extrinsic evidence that may be considered in construing a patent claim. In the decisions adopting this rule, the Federal Circuit has failed to explain how the holding in the *Abbott* case supports such a rule. Indeed, the holding in the *Abbott* case cannot support this rule.

Thus, even if claim construction precedent were relevant to the disclosure required from a patent term extension applicant, which it is not, such precedent would not support the *per se* rule announced by the Federal Circuit in this case. Rather, precedent from this Court and the *en banc* Federal Circuit permits a court to consider any and all extrinsic evidence as part of claim construction. Accordingly, there would be no basis to deem the information that Pfizer withheld from the Patent Office in seeking a patent term extension *per se* irrelevant and immaterial. Rather, precedent would require an analysis of whether that information satisfied the materiality standard set forth by the Patent Office in 37 C.F.R. § 1.765(a).

The Federal Circuit's decision to engraft additional requirements onto a statute or regulation has been questioned in areas other than that presented in this case. Indeed, the Federal Circuit's decision here to import limitations onto the Patent Office regulations defining material information in a patent term extension proceeding is akin to the Federal Circuit adding a "teaching, suggestion, or motivation" limitation onto the obviousness requirements of 35 U.S.C. § 103(a) – an issue currently before this Court in *KSR Int'l Co. v. Teleflex Inc.*, 126 S. Ct.

2965 (2006) (granting certiorari). For this additional reason, the present case has implication beyond the facts presented and impacts the process by which the Federal Circuit interprets the statutes and regulations that are presented before it.

Furthermore, the new *per se* rule should be understood as part of the Federal Circuit's effort to avoid its own struggles in assessing the materiality of an applicant's omission of material fact while appearing, *ex parte*, before the Patent Office. In *Purdue Pharma L.P. v. Endo Pharmaceuticals Inc.*, 410 F.3d 690, 701 (Fed. Cir. 2005), a Federal Circuit panel initially upheld a determination that the asserted patents were unenforceable because the applicant had intentionally withheld data that was material to patentability.[16] Thereafter, the panel withdrew its opinion and issued a new opinion explaining that the same data was not of a sufficiently high level of materiality to render the patent unenforceable. 438 F.3d 1123, 1137 (Fed. Cir. 2006). Similarly, in *Nobelpharma AB v. Implant Innovations, Inc.*, 129 F.3d 1463, 1472 (Fed. Cir. 1997), a panel of the Federal Circuit initially concluded that fraud under *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965), exposing the patentee to antitrust liability, required a showing that the patent was obtained through a misrepresentation, but not through an omission. Four months later, the panel withdrew its opinion and issued a new opinion, explaining that *Walker Process* fraud could be premised on an omission.

---

[16] The District Court had ruled the patent unenforceable for inequitable conduct, which requires a showing of intent to deceive. In contrast, invalidity of a patent term extension, at issue here, requires only that the duty of disclosure was violated through gross negligence. 37 C.F.R. § 1.765(c).

141 F.3d 1059, 1070 (Fed. Cir. 1998). While these cases evidence the Court's internal struggles with the standards for assessing materiality of omitted information, they do not justify the judicial shortcut crafted in this case.

The Federal Circuit's new *per se* rule permits an applicant to omit its own (and the Patent Office Board's) prior inconsistent statements merely because those statements were made while pursuing a different patent. Thus, while this *per se* rule simplifies the materiality inquiry, it does so only by avoiding, altogether, the inquiry into materiality. As such, while the Federal Circuit's *per se* rule may be easy to administer, it is inconsistent with the governing statute and regulation.

The Federal Circuit's decision failing to give effect to the Patent Office's regulation promulgated pursuant to statute is contrary to precedent. Review is necessary to address this important issue and enforce the clear language of the regulation.

III. This Case Presents A Good Vehicle For Resolving The Important Question Presented

This case presents a good opportunity for this Court to review the Federal Circuit's decision to depart from the Patent Office regulation controlling the duty of disclosure required from an applicant for patent term extension for a variety of reasons. First, in this case the Federal Circuit adopted a *per se* rule, categorically defining certain representations by a patentee to the Patent Office and other information as "irrelevant" and not material to a patent term extension proceeding. Because neither the Federal Circuit nor the District Court conducted any substantive review of the information withheld from the Patent Office

during the patent term extension proceeding, the *per se* nature of the Federal Circuit's new rule is glaring.

The Federal Circuit's *per se* rule clearly departs from the disclosure regulations promulgated by the Patent Office pursuant to statute. The Federal Circuit's failure to apply the regulation is an affront to, and undermines, the Patent Office's delegated rulemaking authority. This case clearly demonstrates the Federal Circuit's *per se* rule and its deviation from the applicable regulation.

Second, the "analysis" of the issue by both the Federal Circuit and the District Court shows that neither Court gave effect to the Patent Office regulation. Instead, both Courts imported inapt and ill-founded claim construction precedent into their analyses. The opinions of both Courts amply demonstrate the basis on which they premised their departure from the governing regulation. These opinions present a clear basis for this Court to address the issue presented.

Third, there is no reason to await further percolation of the issue. The Federal Circuit has unequivocally adopted a *per se* rule that the information in question is irrelevant, thereby improperly limiting the Patent Office regulation that should govern disclosure in a patent term extension proceeding. The Federal Circuit's position is settled and is unlikely to evolve over time. Indeed, the Federal Circuit's lack of analysis shows that it viewed the application of its new rule as routine. Because the Federal Circuit has exclusive appellate jurisdiction over any suit challenging the Patent Office's denial of a patent term extension or challenging the validity of a granted patent term extension, there is no reason to believe that further analysis of the Federal Circuit's *per se* rule will be forthcoming. Instead, the Federal Circuit will likely apply the

exact rule announced in this case as settled law. Thus, there is no opportunity for a circuit split to develop and no reason not to review the issue at this time.

Fourth, the issue presented is one of national importance affecting nearly every American. Most of the increase in prescription drug costs is attributable to branded drugs, most of which claim patent protection. Generic alternatives to these branded drugs cost on average half the price of comparable branded drugs. Thus, the availability of generic drugs can deliver large savings to consumers. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration; An FTC Study* 9 (2002).[17] Generic drugs quickly capture the bulk of the market, saving consumers, the federal government, and state governments billions of dollars. Federal Trade Commission, *Prepared Statement of the Federal Trade Commission before the Special Committee on Aging of the United States Senate of Barriers to Generic Entry*, July 20, 2006, pp. 2, 6.[18]

While the Hatch-Waxman Act has proven successful in expediting the approval of generic drugs and bringing these drugs to the public more quickly, the Federal Circuit's new rule regarding disclosure has the potential to thwart that progress. The Federal Circuit's rule allows branded pharmaceutical companies to take flatly inconsistent positions before the Patent Office with impunity. The effect of the Federal Circuit's new rule is to allow branded pharmaceutical companies to extend their patent protection at the expense of the integrity of the Patent Office and

---

[17] *Available at:* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

[18] *Available at:* http://www.ftc.gov/os/2006/07/P052103BarrierstoGenericEntryTestimonySenate07202006.pdf.

the court system. Importantly, this extended patent protection costs the American public and federal and state governments billions of dollars. Review is necessary to prevent branded pharmaceutical companies from using the Federal Circuit's new rule to take inconsistent positions before the Patent Office and to prevent the great social costs that result from these inconsistent positions.

The facts of this case present a striking example of why review is necessary. Lipitor is the most widely prescribed, best selling drug ever, generating global sales of over $12 billion per year. As part of its scheme to shield Lipitor from generic competition, Pfizer represented to the Patent Office that its earlier '893 patent does not cover Lipitor in order to obtain the follow-on '995 patent. Then, Pfizer took a directly contrary position, asserting that the '893 patent covers Lipitor in order to obtain a patent term extension for this patent. In seeking this patent term extension, Pfizer knowingly withheld its earlier, inconsistent representations from the Patent Office, as well as the Board's decision and Pfizer's later '995 patent. Therefore, the Patent Office was denied any opportunity to assess Pfizer's inconsistent positions, and under its incorrect *per se* rule the Federal Circuit did not substantively review Pfizer's inconsistent positions or the other information that Pfizer withheld from the Patent Office. Thus, Pfizer has been allowed to withhold its inconsistent positions from the Patent Office without scrutiny.

Under the controlling regulations, Pfizer's representations were material information that should have been disclosed during the patent term extension proceedings. Pfizer's failure to comply with its disclosure obligations renders the patent term extension invalid. Such a ruling would immediately pave the way for a generic alternative

to Lipitor, saving consumers and governments billions of dollars. Review is necessary at this time to address this important issue.

CONCLUSION

For the reasons stated, the petition for a writ of certiorari should be granted.

Respectfully submitted,

WILLIAM R. ZIMMERMAN
Counsel of Record
DARRELL L. OLSON
JOSEPH M. REISMAN
PAYSON LEMEILLEUR
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main Street, 14th Floor
Irvine, California 92614
(949) 760-0404

Attorneys for Petitioners

457 F.3d 1284

United States Court of Appeals Federal Circuit

06-1179

PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, WARNER-LAMBERT COMPANY, LLC and WARNER-LAMBERT EXPORT, LTD.,

Plaintiffs-Appellees,

v.

RANBAXY LABORATORIES LIMITED and RANBAXY PHARMACEUTICALS INCORPORATED,

Defendants-Appellants.

Rudolf E. Hutz, Connolly Bove Lodge & Hutz LLP, of Wilmington, Delaware, argued for plaintiffs-appellees. With him on the brief were Jeffrey B. Bove, Collins J. Seitz, Jr., Mary W. Bourke, and William E. McShane.

William R. Zimmerman, Knobbe, Martens, Olson & Bear, LLP, of Irvine, California, argued for defendants-appellants. With him on the brief were Darrell L. Olson, John P. Giezentanner, Douglas G. Muehlhauser, and Payson LeMeilleur, of Irvine, California; and Joseph M. Reisman and Darryl H. Steensma, of San Diego, California. Of counsel on the brief were Jay R. Deshmukh and George E. Heibel, Ranbaxy, Inc., of Princeton, New Jersey.

Appealed from: United States District Court for the District of Delaware

Judge Joseph J. Farnan, Jr.

DECIDED: August 2, 2006

Before MICHEL, *Chief Judge*, SCHALL and DYK, *Circuit Judges*.

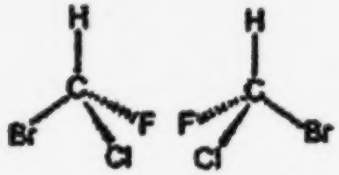
MICHEL, *Chief Judge*.

In this patent case concerning the prescription drug Lipitor®, which is used to reduce low-density lipoprotein (LDL) cholesterol levels, defendants-appellants Ranbaxy Laboratories Limited and Ranbaxy Pharmaceuticals, Inc. (collectively "Ranbaxy") appeal from a final judgment of the United States District Court for the District of Delaware. Plaintiffs-appellees Pfizer Inc., Pfizer Ireland Pharmaceuticals, Warner-Lambert Co., Warner-Lambert Co. LLC, and Warner-Lambert Export, Ltd. (collectively "Pfizer") filed four complaints, later consolidated into a single action, alleging that the product described in Ranbaxy's Abbreviated New Drug Application ("ANDA") No. 76-477 infringed United States Patent Nos. 4,681,893 and 5,273,995 under 35 U.S.C. § 271(e)(2). Ranbaxy appeals the following rulings by the district court: (1) that claim 1 of the '893 patent was infringed; (2) that the '893 patent term extension was not proven invalid; (3) that claim 6 of the '995 patent was infringed; (4) that claim 6 was not proven invalid for failure to comply with § 112, ¶ 4; as anticipated or obvious; or for non-statutory double patenting; and (5) that the '995 patent was not proven unenforceable due to inequitable conduct.

Because we agree with the district court's claim construction of claim 1 of the '893 patent, we affirm the finding of infringement. We also affirm the ruling that the '893 patent term extension was not invalid. With respect to the '995 patent, however, we reverse on the question of invalidity under § 112, ¶ 4 and find the other issues moot.

I. BACKGROUND

Stereochemistry is the study of the three-dimensional structure of molecules. Stereoisomers have the same molecular formula or atomic composition, but different spatial arrangements. Enantiomers are a pair of stereoisomers that are non-superimposable mirror images of each other and often have distinct physical properties.[1] In organic chemistry, enantiomeric pairs include compounds that have one or more chiral centers, i.e., carbon atoms with four non-identical substituent atoms or groups of atoms. For example, the enantiomers of bromochlorofluoromethane are displayed here.



A solid wedge is used to indicate that the chlorine atom is projecting out of the page, while a hashed line indicates that the fluorine atom is behind the page.

To distinguish between different enantiomers of the same compound, chemists use various naming conventions. Enantiomers are sometimes called optical isomers because a pure enantiomer rotates plane-polarized light in a particular direction. If the light rotates clockwise, then that enantiomer is labeled "(+)" or "d" for dextrorotatory; its counterpart will rotate the light counterclockwise and is labeled "(-)" or "l" for levorotatory. A racemate (or racemic mixture) is an equal mixture of two enantiomers. A racemate is labeled "(±)" because it is not optically active

[1] Thalidomide is a well-known example: one enantiomer is effective against morning sickness while the other causes birth defects.

(i.e., will not rotate plane-polarized light in either direction since its constituent enantiomers cancel each other out). Another system labels biochemical molecules "D" or "L" (unrelated to the labels "d" and "l", described above) by reference to the isomers of glyceraldehyde. Yet another nomenclature system labels each chiral center "R" or "S" according to Cahn-Ingold-Prelog priority rules.[2] Racemates are designated "RS" because they are comprised of both R-enantiomers and S-enantiomers.

The terms "cis" and "trans" refer to the relative spatial arrangement of two particular substituents: "cis" means they are on the same side of a plane, while "trans" means they are on opposite sides. In organic compounds, the "plane" is typically a central ring structure. If there are two chiral centers on the aromatic ring, then there are four possible isomers: R-trans, S-trans, R-cis and S-cis. An equal mixture of R-trans and S-trans enantiomers is called the trans-racemate. An equal mixture of R-cis and S-cis enantiomers is called the cis-racemate.

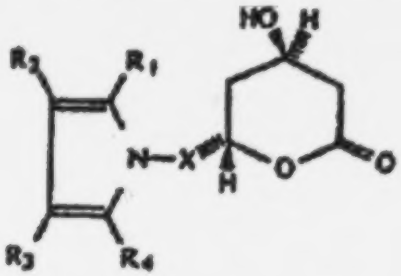
* * *

Pfizer asserted claims 1-4, 8, and 9 of the '893 patent. Claim 1 is the only independent claim. It recites a compound

---

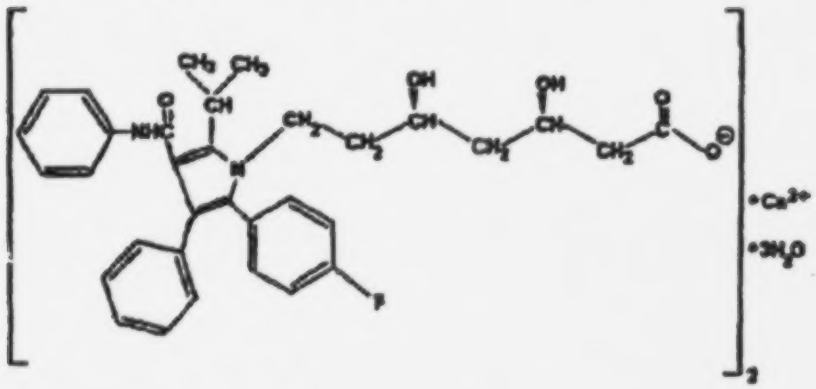
[2] These rules are briefly summarized as follows. Each substituent is assigned a "priority" based on the molecular weight of the atom closest to the chiral center. If more than one substituent starts with the same type of atom, then the molecular weight of the next closest atom is used as a tiebreaker, so an ethyl group ($-C_2H_5$) has a higher priority than a methyl group ($-CH_3$). If there are multiple bonds, the atoms are counted once for each bond so a vinyl group ($-CH=CH_2$) has a higher priority than an ethyl group ($-C_2H_5$). The lowest priority (i.e., lowest molecular weight) substituent is then pointed away from the viewer. If the remaining three substituents are arranged from highest priority to lowest priority in a clockwise direction, then the molecule is labeled "R." If counterclockwise, then it is labeled "S."

having structural formula I (as shown), where there is a pyrrole ring on the left with four substituent groups (labeled R_1, R_2, R_3, and R_4), a pyran (or lactone) ring on the right and an alkyl chain (labeled X) joining the two rings.



Claim 1 expressly defines the possible substituent groups represented by X, R_1, R_2, R_3, and R_4. Claim 1 also covers "a hydroxyl acid or pharmaceutically acceptable salts thereof, corresponding to the opened lactone ring of the compounds of structural formula I above."

Originally, the '893 patent was to expire on May 30, 2006, but Pfizer filed for a patent term extension pursuant to 35 U.S.C. § 156. Pfizer presented evidence that the active ingredient in Lipitor® is atorvastatin calcium or [R-(R*,R*)]-2-(4-fluorophenyl)-β,σ-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)carbonyl]-1H-pyrrole-1-heptanoic acid, calcium salt (2:1) trihydrate. Its structural formula is:



On July 15, 1998, the United States Patent and Trademark Office ("PTO") agreed that this compound was within the scope of the '893 patent and extended the patent term to September 24, 2009.

As for the '995 patent, Pfizer only asserted dependent claim 6.[3] The relevant claims are:

> 1. [R-(R*,R*)]-2-(4-fluorophenyl)-β,σ-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)-carbonyl]-1H-pyrrole-1-heptanoic acid[4] or (2R-trans)-5-(4-fluorophenyl)-2-(1-methylethyl)-N,4-diphenyl-1-[2-(tetrahydro-4-hydroxy-6-oxo-2H-pyran-2-yl)ethyl]-1H-pyrrole-3-carboxamide;[5] or pharmaceutically acceptable salts thereof.
>
> 2. A compound of claim 1 which is [R-(R*R*)]-2-(4-fluorophenyl)-β-σ-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)carbonyl]-1H-pyrrole-1-heptanoic acid.
>
> 6. The hemicalcium salt of the compound of claim 2.

A bench trial commenced on November 30, 2004. The district court issued its findings of fact and conclusions of law on December 16, 2005, concluding that both patents were infringed, not invalid and not unenforceable. *Pfizer Inc. v. Ranbaxy Labs.*, 405 F. Supp. 2d 495 (D. Del. 2005). Judgment was entered on January 4, 2006. The next day,

---

[3] At oral argument, counsel for Ranbaxy revealed that Pfizer had entered into a covenant not to sue under independent claim 1 of the '995 patent. The parties also stipulated that claim 6 was a dependent claim.

[4] This compound is also known as atorvastatin acid.

[5] This compound is also known as atorvastatin lactone.

Ranbaxy filed its notice of appeal. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

II. DISCUSSION

Following a bench trial, a district court's conclusions of law are reviewed de novo while its findings of fact are reviewed for clear error. *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1343-44 (Fed. Cir. 2002). A factual finding is clearly erroneous if, despite some supporting evidence, "the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 395 (1948).

A. '893 Patent.

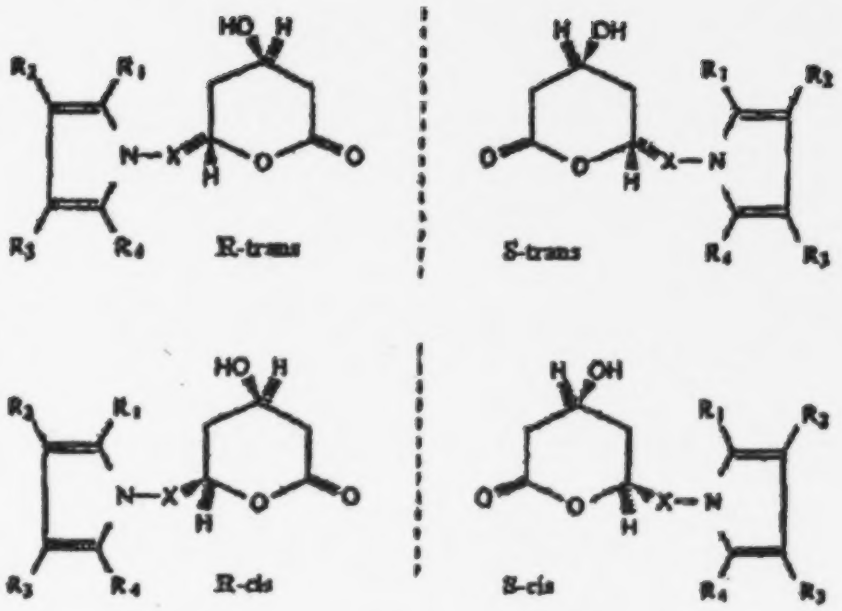
1. Correct Claim Construction.

Claim construction is a question of law reviewed de novo. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454-56 (Fed. Cir. 1998) (en banc). We determine the ordinary and customary meaning of claim terms as understood by a person of ordinary skill in the art, using the methodology first set forth in *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582-83 (Fed. Cir. 1996), and reaffirmed in *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-19 (Fed. Cir. 2005) (en banc). The subsequent infringement analysis is reviewed "for clear error if performed by the court and for substantial evidence if performed by a jury." *Young Dental Mfg. Co. v. Q3 Special Prods.*, 112 F.3d 1137, 1141 (Fed. Cir. 1997).

The parties agree that under the district court's claim construction, Ranbaxy's ANDA product infringes claim 1.

On appeal, Ranbaxy argues that the district court erred in construing structural formula I "to embrace all trans-form isomers, including enantiomeric atorvastatin calcium" in lieu of accepting its proffered construction limiting claim 1 to racemates. *Pfizer,* 405 F. Supp. 2d at 507. Instead, Ranbaxy contends that structural formula I is limited to racemates, because (1) one skilled in the art would represent a racemate by depicting one of its constituent enantiomers; (2) the specification only discloses reaction sequences that produce racemates; (3) during prosecution of foreign counterparts to the '893 patent, the patentee represented that its references to "trans" should be read as "trans-(±);" and (4) during prosecution of the '995 patent, the patentee argued that the '893 patent was limited to mixtures of enantiomers rather than the R-isomer. Thus, Ranbaxy argues, its ANDA product does not infringe claim 1 of the '893 patent because it is the R-enantiomer of atorvastatin calcium. We disagree.

It is undisputed that the drawing in claim 1 depicts an R-trans enantiomer. All four isomers of structural formula I are shown here.



These compounds are labeled "R" and "S" based on the stereochemistry of the chiral center at the top (i.e., 4-hydroxy position) of the pyran-2-one ring. The "cis" and "trans" designations refer to the spatial relationship between the hydroxyl group (-OH) and the alkylpyrrole group relative to the plane of the pyran-2-one ring.

The district court correctly observed that the '893 patent consistently describes the invention as a class of "trans" compounds. The specification of the '893 patent explains at col. 3, ll. 45-54:

> The compounds of structural formula I above possess two asymmetric carbon centers ... [which] gives rise to four possible isomers, two of which are the R-cis- and S-cis-isomers and the other two of which are the R-trans- and S-trans-isomers. This invention contemplates only the trans-form of the compounds of formula I above.

We read this language to mean that the invention would otherwise encompass all four isomers of the compounds of structural formula I, but for the patentee's express disclaimer of the R-cis- and S-cis-isomers. There is no further disavowal of claim scope that would limit the '893 patent to trans-racemates. Indeed, as noted by the district court, the terms "racemate" or "racemic mixture" do not appear in the '893 patent; nor is claim 1, unlike claim 5, limited by a "trans-(±)" designation. In sum, the district court correctly found that no intrinsic evidence limits claim 1 of the '893 patent to trans-racemates, as opposed to an R-trans enantiomer, an S-trans enantiomer or any (equal or unequal) mixtures thereof.

We are not persuaded by Ranbaxy's arguments to the contrary. First, even accepting Ranbaxy's contention that a racemate is commonly represented by depicting one of its constituent enantiomers, it does not follow that the depiction of an R-enantiomer always represents *only* a racemate. Here, only an R-trans enantiomer is depicted in the '893 patent, yet the specification expressly indicates that there are four possible isomers of the compounds of structural formula I and limits the invention to the trans-form. If one skilled in the art would have understood the drawing of structural formula I to limit the scope of claim 1 to trans-racemates, then an express disclaimer of the cis-form would not have been necessary.

Second, while the examples do describe reaction sequences that produce racemates, restricting claim 1 on this basis would improperly import limitations from the specification into the claims, which should be avoided unless the patentee clearly "intends for the claims and the embodiments in the specification to be strictly coextensive." *Phillips,* 415 F.3d at 1323. But here, the specification, at

col. 10, ll. 36-38, states that "[t]hese examples are illustrative and are not to be read as limiting the scope of the invention as it is defined by the appended claims."

Third, we agree with the district court's conclusion that the statements made during prosecution of foreign counterparts to the '893 patent are irrelevant to claim construction because they were made in response to patentability requirements unique to Danish and European law. *See TI Group Auto. Sys. (N. Am.), Inc. v. VDO N. Am. LLC,* 375 F.3d 1126, 1136 (Fed. Cir. 2004). Likewise, statements made during prosecution of the later, unrelated '995 patent cannot be used to interpret claims of the '893 patent. *See Goldenberg v. Cytogen, Inc.,* 373 F.3d 1158, 1167-68 (Fed. Cir. 2004) (finding statements in another patent or its prosecution history irrelevant to claim construction "[a]bsent a formal relationship or incorporation during prosecution" of the patent at issue); *cf. Abbott Labs. v. Dey L.P.,* 287 F.3d 1097, 1104-05 (Fed. Cir. 2002) (finding arguments made during prosecution of a commonly-owned but unrelated patent did not create prosecution history estoppel). Finally, insofar as Ranbaxy restates the same argument under the guise of judicial estoppel, we are not persuaded.

Because claim 1 was correctly construed to include the enantiomeric trans-forms of the compounds of structural formula I, we affirm the finding of infringement.

2. Term Extension.

Under the Hatch-Waxman Act, if a patented product has been subject to a regulatory review period before its commercial marketing or use, an extension of the patent term may be obtained. 35 U.S.C. § 156(c). In applying for a

patent extension, the patentee has a duty of candor and good faith towards the PTO and must disclose any "material information adverse to a determination of entitlement to the extension sought." 37 C.F.R. § 1.765(a). The Director of the PTO is charged with deciding whether the patent is entitled to term extension, a decision which is given "great deference." *Glaxo Operations UK Ltd. v. Quigg,* 894 F.2d 392, 399 (Fed. Cir. 1990).

On appeal, Ranbaxy asserts that, when correctly construed, the '893 patent does not cover enantiomeric atorvastatin calcium, i.e., the active ingredient in Lipitor®, so it was not eligible for a patent term extension under 35 U.S.C. § 156. In the alternative, Ranbaxy argues that the term extension is invalid due to inequitable conduct because Pfizer failed to disclose the statements Warner-Lambert made during prosecution of the '995 patent and the foreign counterparts to the '893 patent.

Ranbaxy's first argument depends on its proffered claim construction, which we have already rejected. As to its allegations of inequitable conduct, the district court found that the allegedly withheld information was not material, and consequently did not need to be disclosed to the PTO, because those statements were "irrelevant to a determination of the scope of the claims of the '893 patent." *Pfizer,* 405 F. Supp. 2d at 512. This factual finding was not clearly erroneous. We thus agree that Ranbaxy failed to establish by clear and convincing evidence that the term extension was invalid.

B. '995 Patent.

With respect to the '995 patent, numerous issues have been raised on appeal. Rather than considering them in

the order presented by the appellants, we first direct our attention to the question of validity under 35 U.S.C. § 112, ¶ 4, which provides:

> Subject to the following paragraph [concerning multiple dependent claims], a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

As described above, Pfizer only asserted dependent claim 6 of the '995 patent. This claim reads: "The hemicalcium salt of the compound of claim 2." Claim 2, in turn, is dependent on claim 1, which recites the following compounds: (1) atorvastatin acid; or (2) atorvastatin lactone; or (3) pharmaceutically acceptable salts thereof. Claim 2 itself, however, only recites atorvastatin acid. Notably, it does *not* include the pharmaceutically acceptable salts of atorvastatin acid.[6] Ranbaxy asserts that the district court erred in refusing to invalidate claim 6, even though it does not "incorporate by reference all the limitations of the claim to which it refers" and "then specify a further limitation of the subject matter," as required by § 112, ¶ 4. In other words, claim 6 does not narrow the scope of claim 2; instead, the two claims deal with non-overlapping subject matter.

---

[6] Theoretically, a claimed acid could be liberally construed to include the corresponding salts. *See Merck & Co., Inc. v. Teva Pharms. USA, Inc.*, 347 F.3d 1367, 1372 (Fed. Cir. 2003). But here, given the absence of the "pharmaceutically acceptable salts thereof" language which was used in claim 1, the intrinsic evidence would not have supported such an interpretation of claim 2.

The district court explicitly recognized that "there may be a technical problem in the drafting of claim 6." *Pfizer,* 405 F. Supp. 2d at 508. Yet, it declined to find that "this drafting problem is sufficient to render the claim invalid if the claim is read consistently with its meaning to those skilled in the art" because it was unable to find any Federal Circuit precedent applying § 112, ¶ 4 to invalidate a patent. *Id.* at 508-09. The district court understood § 112, ¶ 4 "to be limited to matters of form, rather than matters of substance," noting that the PTO treats a claim that fails to comply with this provision "as a matter to be addressed through an objection" rather than rejected as unpatentable. *Id.* at 509. In any event, it emphasized that no objections were made to claim 6, (or any of the other similarly-worded dependent claims), during prosecution. *Id.* at 509 n.7.

It is true that at the time the district court wrote its opinion, there was no applicable Federal Circuit precedent. More recently, however, we have suggested that a violation of § 112, ¶ 4 renders a patent invalid just as violations of other paragraphs of § 112 would. *Curtiss-Wright Flow Control Corp.,* 438 F.3d 1374, 1380 (Fed. Cir. 2006). In *Curtiss-Wright,* the issue was one of claim differentiation. The court reasoned that "reading an additional limitation from a dependent claim into an independent claim would not only make that additional limitation superfluous, it might render the dependent claim invalid" for failing to add a limitation to those recited in the independent claim, as required by 35 U.S.C. § 112, ¶ 4. *Id.* Indeed, "[i]nvalidity of the patent or any claim in suit for failure to comply with *any* requirement of sections 112 or 251 of this title" is expressly included

among the available defenses to an infringement suit. 35 U.S.C. § 282(3) (emphasis added).

We recognize that the patentee was attempting to claim what might otherwise have been patentable subject matter.[7] Indeed, claim 6 could have been properly drafted either as dependent from claim 1 or as an independent claim – i.e., "the hemicalcium salt of atorvastatin acid." But, we "should not rewrite claims to preserve validity." *Nazomi Commc'ns, Inc. v. Arm Holdings, PLC,* 403 F.3d 1364, 1368 (Fed. Cir. 2005); *see also Rhine v. Casio, Inc.,* 183 F.3d 1342, 1345 (Fed. Cir. 1999) ("[I]f the only claim construction that is consistent with the claim's language and the written description renders the claim invalid, then . . . the claim is simply invalid."). Ranbaxy correctly argues that claim 6 fails to "specify a further limitation of the subject matter" of the claim to which it refers because it is completely outside the scope of claim 2. We must therefore reverse the district court with respect to this issue and hold claim 6 invalid for failure to comply with § 112, ¶ 4.

Although the district court was reluctant to find the fourth paragraph of § 112 to be an invalidating provision, doing so does not exalt form over substance. Rather, it is consistent with the overall statutory scheme that requires applicants to satisfy certain requirements before obtaining a patent, some of which are more procedural or technical

---

[7] The district court found that claim 6 was unambiguous to the extent that the patentee intended to claim the hemicalcium salt of atorvastatin acid. *Pfizer,* 405 F. Supp. 2d at 507. The court further recognized that "[a]s a matter of standard chemical nomenclature, chemists typically refer to a salt of an acid, even though they are aware that the complete acid is technically no longer present in the salt form." *Id.* at 508.

than others. *See, e.g.*, 35 U.S.C. § 102(b) & (d) (establishing statutory one-year bars to patentability); 35 U.S.C. § 111(a)(2)(C) (requiring submission of an oath by the applicant); 35 U.S.C. § 111(a)(3) (requiring submission of a fee with the application); 35 U.S.C. § 116 (requiring joint inventors to apply for a patent jointly).

In light of this holding, appellants' remaining arguments concerning the '995 patent are rendered moot. We therefore decline to reach the remaining issues raised.

III. CONCLUSION

For the aforementioned reasons, we affirm-in-part, reverse-in-part and remand so the district court can modify the permanent injunction in a manner consistent with this opinion.

AFFIRMED-IN-PART, REVERSED-IN-PART and REMANDED.

405 F.Supp.2d 495

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, WARNER-LAMBERT COMPANY, LLC, and WARNER-LAMBERT EXPORT, LTD.,	:	Civil Action No. 03-209-JJF (Consolidated)
Plaintiffs,	:	
v.	:	
RANBAXY LABORATORIES LIMITED and RANBAXY PHARMACEUTICALS, INC.,	:	
Defendants.	:	

Rudolf E. Hutz, Esquire, Jeffrey B. Bove, Esquire, Collins J. Seitz, Jr., Esquire and Mary W. Bourke, Esquire of CONNOLY BOVE LODGE & HUTZ LLP, Wilmington, Delaware
Attorneys for Plaintiffs.

Steven J. Balick, Esquire and John G. Day, Esquire of ASHBY & GEDDES, Wilmington, Delaware.
Of Counsel: Darrell L. Olson, Esquire, John P. Giezentanner, Esquire, Douglas G. Muehlhauser, Esquire, William R. Zimmerman, Esquire, Payson LeMeilleur, Esquire, Sheila N. Swaroop, Esquire, Darryl H. Steensma, Esquire and Walter S. Wu, Esquire of KNOBBE, MARTENS, OLSON & BEAR, LLP, Irvine, California.
Jay R. Deshmukh, Esquire and George E. Heibel, Esquire of RANBAXY, INC., Princeton, New Jersey.
Attorneys for Defendants.

MEMORANDUM OPINION

December 16, 2005
Wilmington, Delaware

Farnan, District Judge. [/s/ Joseph J Farnan J]

This action was brought by Plaintiffs, Pfizer Inc., Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, Warner-Lambert Company, LLC and Warner-Lambert Export, Ltd. (collectively, "Pfizer") against Defendants, Ranbaxy Laboratories Limited and Ranbaxy Pharmaceuticals Incorporated (collectively, "Ranbaxy") for infringement of U.S. Patent No. 4,681,893 (the "'893 patent") and U.S. Patent No. 5,273,995 (the "'995 patent"). The '893 and '995 patents pertain to an atorvastatin calcium pharmaceutical composition sold by Pfizer under the registered name Lipitor®. Lipitor® is prescribed by doctors for the treatment of elevated cholesterol and is the largest selling pharmaceutical in history. This lawsuit arises in connection with Abbreviated New Drug Application ("ANDA") No. 76-477 filed by Ranbaxy seeking to commercially manufacture, use and sell a drug product containing atorvastatin calcium as its active agent. Pfizer filed four Complaints against Ranbaxy alleging that Ranbaxy's proposed ANDA product infringes the '893 and '995 patents under 35 U.S.C. § 271(e)(2). These Complaints have been consolidated into this action. By its Complaints, Pfizer has asserted two patents against Ranbaxy, the '893 patent and the '995 patent. Specifically, Pfizer alleges infringement of claims 1-4, 8 and 9 of the '893 patent and claim 6 of the '995 patent.

In response to Pfizer's Complaints, Ranbaxy filed an Answer and several Counterclaims. Ranbaxy alleges that it does not infringe either the '893 or '995 patents. Ranbaxy

also challenges the validity of the patent term extension granted by the PTO for the '893 patent. With regard to the '995 patent, Ranbaxy contends that the asserted claim of the '995 patent, claim 6, is invalid for double patenting, obviousness and anticipation. Ranbaxy also contends that the '995 patent is unenforceable as a result of inequitable conduct by Warner-Lambert Company before the PTO.

The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338, because this action arises under the patent laws of the United States. The Court also has subject matter jurisdiction over Ranbaxy's counterclaims pursuant to 28 U.S.C. §§ 1338, 2201 and 2202. The parties have submitted to the personal jurisdiction of the Court, and venue in this District is appropriate pursuant to 28 U.S.C. §§ 1391 and 1400.

The Court conducted a bench trial on the issues presented by the parties.[1] This Memorandum Opinion constitutes the Court's findings of fact and conclusions of law on the issues raised during trial.

BACKGROUND

I. The Parties

Pfizer Inc. is a Delaware corporation having a place of business in Morris Plains, New Jersey and corporate offices in New York City. Warner-Lambert Company was a Delaware corporation that became a wholly-owned

[1] The bench trial began on November 11, 2004 and was completed on December 13, 2004. Post-trial briefing was completed on April 4, 2005. In addition, two post-trial evidentiary motions (D.I. 314, 319) were filed by Pfizer, which will be addressed separately by the Court.

subsidiary of Pfizer Inc. on June 19, 2000. Warner-Lambert Company was then converted into Warner-Lambert Company, LLC, a Delaware limited liability company. Warner-Lambert Export, Ltd., is a corporation formerly organized under the laws of Ireland with a registered office located in Dublin, Ireland. Pfizer Ireland Pharmaceuticals is a partnership between C.P. Pharmaceuticals International, C.V., a limited partnership under the laws of the Netherlands, and Pfizer Overseas Pharmaceuticals, a private limited company incorporated in Ireland. Pfizer Ireland Pharmaceuticals is a wholly-owned subsidiary of Pfizer Inc. with registered offices in Dublin, Ireland. Through Parke-Davis Pharmaceuticals Research, a division of Warner-Lambert Company, Pfizer holds an approved New Drug Application for the atorvastatin calcium pharmaceutical composition sold under the name Lipitor®.

Ranbaxy Pharmaceuticals Incorporated is a Delaware corporation with a place of business located in Princeton, New Jersey. Ranbaxy Laboratories Limited is a corporation of India with corporate offices located in New Delhi, India. Ranbaxy Pharmaceuticals Incorporated is a wholly-owned subsidiary of Ranbaxy Laboratories Limited.

II. The Patents Generally

A. The '893 Patent

The '893 patent is entitled "Trans-6-[2-(3- OR 4-carboxamido-substituted pyrrol-1-yl)alkyl]-4-hydroxypyran-2-one inhibitors of cholesterol synthesis." The inventor of the '893 patent is Dr. Bruce D. Roth. Pfizer has identified to the Food and Drug Administration that the '893 patent covers the atorvastatin calcium composition sold by Pfizer

since 1997 under the name Lipitor®. The '893 patent was to expire on May 30, 2006; however, the PTO granted an extension pursuant to 35 U.S.C. § 156, extending the expiration date of the '893 patent to September 24, 2009, excluding a six month pediatric extension.

B. The '995 Patent

The '995 patent is entitled "[R-(R*,R*)]-2-(4-fluorophenyl)-β, σ-dihydroxy-5-(1-methylethyl-3-phenyl-4-[(phenylamino) carbonyl]-1H-pyrrole-1-heptanoic acid, its lactone form and salts thereof." Dr. Bruce D. Roth is also the inventor of the '995 patent. The compound covered by the '995 patent is commonly referred to as atorvastatin calcium. The '995 patent expires on December 28, 2010.

DISCUSSION

I. Claim Construction Of The '893 And '995 Patents

A. The Legal Principles Of Claim Construction

Claim construction is a question of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977-78 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370, 388-90 (1996). When construing the claims of a patent, a court considers the literal language of the claim, the patent specification and the prosecution history. *Markman*, 52 F.3d at 979. In *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-1317 (Fed. Cir. 2005), the Federal Circuit reaffirmed the claim construction principles set forth in *Markman* and reemphasized that the specification is the single best source for discerning the meaning of a claim.

A court may consider extrinsic evidence, including expert and inventor testimony, dictionaries, and learned treatises, in order to assist it in understanding the underlying technology, the meaning of terms to one skilled in the art and how the invention works. *Phillips,* 415 F.3d at 1318-319; *Markman,* 52 F.3d at 979-80 (citations omitted). However, extrinsic evidence is considered less reliable and less useful in claim construction than the patent and its prosecution history. *Phillips,* 415 F.3d at 1318-319 (discussing "flaws" inherent in extrinsic evidence and noting that extrinsic evidence "is unlikely to result in a reliable interpretation of a patent claim scope unless considered in the context of intrinsic evidence").

In addition to these fundamental claim construction principles, a court should also interpret the language in a claim by applying the ordinary and accustomed meaning of the words in the claim. *Envirotech Corp. v. Al George, Inc.,* 730 F.2d 753, 759 (Fed. Cir. 1984). If the patent inventor clearly supplies a different meaning; however, then the claim should be interpreted according to the meaning supplied by the inventor. *Markman,* 52 F.3d at 980 (noting that patentee is free to be his own lexicographer, but emphasizing that any special definitions given to words must be clearly set forth in the patent). If possible, claims should be construed to uphold validity. *In re Yamamoto,* 740 F.2d 1569, 1571 n.* (Fed. Cir. 1984) (citations omitted).

B. Scientific Background/Terminology Needed For Claim Construction

The parties' claim construction disputes impact the field of stereochemistry, a subfield of chemistry. Stereochemistry is concerned with the three-dimensional

structure of organic molecules in space. An isomer is one of several molecular entities that have the same atomic composition or molecular formula, but a different stereochemical formula, meaning the atoms are the same in number and type but different in their spatial arrangement. Stereoisomers are compounds that have the same atoms and the same connection pattern of atoms or groups of atoms, but are different in the way that those atoms or groups of atoms are arranged in space. Enantiomers are stereoisomers that are non-superimposable mirror images of each other. Enantiomers have identical physical properties, including solubilities and melting points, with the exception of their interactions with chiral matter and plane-polarized light. A racemate, or racemic mixture, is an equal mixture of two enantiomers, such that it contains 50% of one enantiomer and 50% of its opposite enantiomer. Racemates and enantiomers are distinct compounds, and in general, have different physical properties such as solubility and melting points.

Optical activity is a compound's ability to rotate plane-polarized light. A pure enantiomer rotates plane-polarized light in only one direction to the maximal amount permitted by that molecule. An unequal mixture of two opposite enantiomers is optically active and the degree of optical rotation reflects the percentage of each enantiomer present in the mixture. In a racemate, which is an equal mixture of two opposite enantiomers, the compound is not optically active, because the optical rotations of the enantiomers cancel each other out.

Chemists name and describe racemates and enantiomers with certain symbols and designations. In a molecule containing one asymmetric center, one enantiomer is designated as the R-enantiomer and its opposite is the

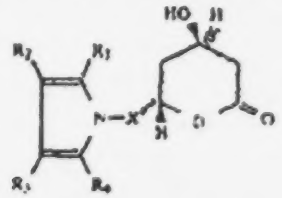
S-enantiomer. A racemate is designated as an "RS" structure, because it contains equal amounts of R and S enantiomers. A pure enantiomer is optically active because it rotates plane-polarized light either clockwise or counterclockwise. Chemists use a "+" symbol for the clockwise direction and a "-" symbol for the counterclockwise direction. A racemate is not optically active, and thus, chemists use the "±" to indicate a racemate.

The term "trans" is used to define the relationship of two groups to one another and indicates that two substituents are on opposite sides of a plane in a chemical structure. The term "cis" indicates that the two substituents are on the same side of the plane. Thus, the terms "cis" and "trans" describe relative stereochemistry.

Typically, when compounds are made synthetically in a lab, they are made as racemates. The process of isolating the enantiomers from a racemate is known as resolution.

C. The Claim Construction Of The '893 Patent

Pfizer asserts Claims 1-4, 8 and 9 of the '893 patent against Ranbaxy's ANDA product. Claim 1 is the only independent claim of the '893 patent and recites a compound of structural formula I drawn as:



This compound has a backbone of two rings joined by a bridge, designated as "X." The five-membered ring on the left contains a nitrogen atom designated as "N" and is a

"pyrrole" ring. The six-membered ring on the right contains an oxygen atom ("O") and is a "pyran" or "lactone" ring. The left-hand ring has four possible substituents designated R_1 through R_4. Claim one of the patent designates the possible substituents for each of R_1, R_2, R_3, and R_4. The patent also designates the particular groups for X.

The parties' only claim construction dispute with respect to the '893 patent is what structural formula I represents. Ranbaxy contends that structural formula I represents only a genus of racemates. Pfizer agrees that claim 1 represents racemates, but contends that it is not limited to racemates. Pfizer contends that claim 1 also represents R-trans enantiomers, S-trans enantiomers and unequal mixtures of R-trans and S-trans enantiomers. The parties agree that structural formula I depicts an enantiomer; however, the parties also agree that this is not the meaning of structural formula I and that the meaning of structural formula I must be determined by reference to the context of the '893 patent.

After considering the claim language, the specification and the prosecution history of the '893 patent, the Court concludes that the '893 patent is not limited to racemates and embraces the two individual trans-form isomers, the R-trans and S-trans, as well as their transform mixtures, including racemates. The Title, Abstract and Background sections of the '893 patent describe the invention as "trans" compounds. The Summary of the Invention then describes "certain trans" compounds and then defines the "broadest aspect of the present invention" as "compounds of structural formula I." DTX-13, col. 2, l. 2. In the Detailed Description section, the specification goes on to describe the "compounds of the present invention" as a

"class of trans . . . " compounds. *Id.* at col. 3, l. 36-37. The patent expressly states:

> The compounds of structural formula I above possess two asymmetric carbon centers, one at the 4-hydroxy position of the pyran-2-one ring, and the other at the 6-position of the pyran 2-one ring where the alkylpyrrole group is attached. This asymmetry gives rise to *four possible isomers, two of which are the R-cis- and S-cis-isomers and the other two of which are the R-trans- and S-trans-isomers. This invention contemplates only the trans-form of the compounds of formula I above.*

Id. at col. 3, l. 45-54 (emphasis added). The Court understands this language to contemplate all trans-form compounds, including the individual R-trans isomer. In reaching this conclusion, the Court observes that the terms "racemate" or "racemic mixture" do not appear anywhere in the '893 patent, and there are no words of limitation or chemical symbols used in claim 1 to restrict the meaning of "trans" or "trans-form" to the trans-racemate form.[2]

In contrast to claim 1, dependent claim 5 of the '893 patent uses the designation "Trans-(±)" to designate a racemic mixture. Ranbaxy contends that the use of this

---

[2] The expert witnesses of both Pfizer and Ranbaxy agree that the term "trans" refers to two groups on opposite sides of the plane. The term does not denote any specific three dimensional configuration such as only R-trans, only S-trans, or only a 50/50 mixture or racemate. (Clive Tr. 1553:5-1554:9; Roush Tr. 884:7-23). Further, both experts also agree that each of the individual R-trans and S-trans isomers, along with all mixtures of those isomers are in the "trans-form." (Clive Tr. 1572:12-1574:15; Roush Tr. 233:23-234:5, 882:2-883:24).

terminology should not be dispositive, because the patent identifies racemates in its examples without using the "±" designation. However, it is well-established that a claim is not limited by its examples or embodiments, unless the intrinsic evidence suggests an intent to so limit the claim. *See e.g. Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004); *Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1357 (Fed. Cir. 2004) ("[T]he applicant's choice to describe only a single embodiment does not mean that the patent clearly and unambiguously disavowed other embodiments."). As discussed by the Court in more detail below, the express language of the patent indicates no intention to limit the claims to the compounds exemplified. Further, that the "±" designation was used in the express language of claim 5 and not in the language of the other claims suggests to the Court that the inventor knew how to limit a claim to a racemate, but chose not to so restrict the other claims of the patent. *Liebel-Flarsheim*, 358 F.3d at 910 ("The presence of a dependent claim that adds a particular limitation raises a presumption that the limitation in question is not found in the independent claim.") (citations omitted); *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1119 (Fed. Cir. 2004) (recognizing that "when an applicant uses different terms in a claim it is permissible to infer that he intended his choice of different terms to reflect a differentiation in the meaning of those terms"). In the Court's view, a contrary conclusion would make the "±" term in claim 5 surplusage. *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 93 F.3d 1572, 1579 (Fed. Cir. 1996)

Ranbaxy contends that "by common convention, a racemate *can* be represented by depicting one of its constituent enantiomers." (D.I. 292 at 4) (emphasis added).

Ranbaxy is correct that a depiction of an enantiomer can sometimes include or specify a racemate, but Ranbaxy has not demonstrated that, to one skilled in the art, such a depiction always or even usually specifies a racemate. Further, the fact that external sources may use an enantiomer to indicate a racemate does not overcome the intrinsic evidence of the '893 patent that the claimed invention is not limited to racemates. *Phillips,* 415 F.3d at 1319 (recognizing, to the extent extrinsic evidence is used in claim construction, it must be considered in the context of the intrinsic evidence to be reliable).

Ranbaxy also seeks to limit the claimed invention to racemates because the reaction sequences and examples of the '893 patent are racemic. As the Court has concluded, however, the '893 patent is not limited to its examples and provides no indication that it should be so limited. For example, Table 1 of the patent reports results for test procedures used to determine the biological activity of examples of formula 1. However, the patent expressly identifies the Table 1 examples as "representative examples." Similarly, the '893 patent presents four working examples which also produce racemic mixtures; however, the patent states that these four examples "illustrate particular methods for preparing compounds in accordance with this invention. *These examples are illustrative and are not to be read as limiting the scope of the invention . . .*" DTX-13, col. 10, ll. 33-38 (emphasis added). Because the patent expressly evidences an intention that these examples be illustrative and the law disfavors limiting the patent based on its examples, the Court concludes that the reaction sequences and examples contained in the '893 patent do not limit the claimed invention to a racemic mixture or racemate.

Ranbaxy contends that if the Court accepts Pfizer's construction of the '893 patent, the patent is invalid for lack of written description, because the patent does not disclose any methods for making enantiomers. In *Regents of the University of California v. Eli Lilly & Co.,* 119 F.3d 1559, 1568 (Fed. Cir. 1997), the Federal Circuit recognized that "in claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass." However, the Federal Circuit also acknowledged in *Lilly* its holding in *Utter v. Hiraga,* 845 F.2d 993, 998-999 (Fed. Cir. 1988), that "[a] specification may, within the meaning of § 112 ¶ 1, contain a written description of a broadly claimed invention without describing all species that claim encompasses." While the Federal Circuit declined to extend *Utter* in *Lilly* to claims involving genetic material, it did not abandon its holding for chemical materials noting that in the case of generic formulae, "[o]ne skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus." *Lilly,* 119 F.3d at 1568. In this case, the written description of the '893 patent is a generic formula which the patent specification expressly indicates includes all trans-enantiomers. Ranbaxy acknowledges that one skilled in the art would know how to resolve racemates into their constituent enantiomers, and therefore, the Court concludes that the generic formula description contained in the '893 patent is sufficient to satisfy the written description requirement, regardless of whether the specific isomeric compounds are individually described in the patent.

Ranbaxy also contends that Warner-Lambert's representations during the prosecution of foreign counterparts

to the '893 patent demonstrate that the '893 patent is limited to racemates. During the prosecution of the foreign counterparts to the '893 patent in Denmark and Europe, Warner-Lambert represented that the term "trans-" referred to "trans(±)." However, the Federal Circuit has recognized that "'the varying legal and procedural requirements for obtaining patent protection in foreign countries might render consideration of certain types of representations inappropriate' for consideration in a claim construction analysis of a United States counterpart." *TI Group Auto. Sys. (N. Am.), Inc. v. VDO N. Am., L.L.C.*, 375 F.3d 1126, 1136 (Fed. Cir. 2004) (citations omitted). In the circumstances presented here, the Court finds that Warner-Lambert amended the Danish claims to limit them to racemates in response to the legal and procedural requirements specified by Danish law. Specifically, the Danish examiner found that under Danish law the scope of the claims was "too comprehensive." DTX 241 at P0279442. With respect to the European counterpart, Warner-Lambert made no actual amendments to the claims or specifications, but offered the "trans (±)" designation in response to the examiner's concerns that the chemical nomenclature used in the patents was insufficiently articulated under European laws. The United States PTO raised no such concerns during the prosecution of the '893 patent, and Ranbaxy has not demonstrated to the Court any similarities between the foreign laws and the laws of the United States that would lead the Court to conclude that these changes and/or interpretations were not made in response to the unique aspects of the respective foreign laws under which patentability of the '893 counterparts was sought. Accordingly, the Court is not persuaded that Warner-Lambert's statements during the prosecution of foreign counterparts of the '893 patent are

relevant to the Court's construction of the '893 patent issued in the United States.

In a similar vein, Ranbaxy contends that Pfizer is precluded from pursuing its proposed claim construction of the '893 patent based on statements made by Warner-Lambert during the prosecution of the '995 patent. However, the Federal Circuit has repeatedly held that arguments from a later, unrelated patent prosecution cannot be used to interpret and/or limit an earlier, unrelated and already issued patent.[3] *Integra Lifesciences I, Ltd. v. Merck KGaA,* 331 F.3d 860, 868 (Fed. Cir. 2003), *cert. granted on other grounds,* 125 S. Ct. 823 (2005). Ranbaxy proffers a similar argument under the doctrine of judicial estoppel, but the Court is not persuaded that the principles of judicial estoppel are applicable in this context. Ranbaxy has offered no case law applying the doctrine of judicial estoppel in the context of claim construction, and in the Court's view, application of judicial estoppel in such a context would essentially undercut the Federal Circuit's clear pronouncements in the *Integra* line of cases.

In the alternative, even if the Court were to consider the doctrine of judicial estoppel, the Court concludes that Ranbaxy has not demonstrated its applicability. Whether judicial estoppel applies is determined by regional circuit law. In the Third Circuit, the party asserting the doctrine of judicial estoppel must establish that: "(1) the party to be estopped is asserting a position that is irreconcilably inconsistent with one he or she asserted in a prior proceeding;

---

[3] *See also Abbott Labs. v. Dey, L.P.*, 287 F.3d 1097, 1099-1100, 1104-1105 (Fed. Cir. 2002); *Laitram Corp. v. Cambridge Wire Cloth Co.*, 863 F.2d 885, 862 n. 16 (Fed. Cir. 1988)

(2) the party changed his or her position in bad faith, i.e. in a culpable manner threatening to the Court's authority or integrity; and (3) the use of judicial estoppel is tailored to address the affront to the Court's authority or integrity." *Montrose Med. Group Participating Sav. Plan v. Bulger,* 243 F.3d 773, 777-778 (3d Cir. 2001). Ranbaxy contends that Pfizer's position in this case is irreconcilably inconsistent with its position during the prosecution of the '995 patent. Although there may be a degree of tension between the positions taken by Pfizer in each instance, the Court cannot conclude that those positions are irreconcilably inconsistent. The arguments Pfizer made in the '995 prosecution were directed to the issue of whether the '995 patent claims were anticipated in light of the '893 patent, an analysis which is different from the infringement analysis. Further, the Court is not persuaded that Pfizer's positions demonstrate bad faith or that the use of judicial estoppel is necessary to address an affront to the Court's authority or integrity.

In sum, the Court concludes that its construction of the '893 patent is supported by the specification and the express language of the claims. In contrast, Ranbaxy's proffered construction is primarily based on extrinsic evidence, which is irrelevant to claim construction and inconsistent with the intrinsic evidence of the '893 patent. Accordingly, the Court reads structural formula I of the '893 patent to embrace all trans-form isomers, including enantiomeric atorvastatin calcium.

D. Claim Construction Of The '995 Patent

Pfizer asserts claim 6 of the '995 patent against Ranbaxy's ANDA product. Claim 6 is a dependent claim,

which depends on claim 2, which in turn depends on claim 1. Claim 1 is the only independent claim of the '995 patent. The relevant claims provide:

> 1. [R-(R*,R*)]-2-(4-fluorophenyl)-β, σ-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylmino)-carbonyl]-1H-pyrrole-1-heptanoic acid or (2R-trans)-5-(4-fluorophenyl)-2-(1-methylethyl)-N, 4-diphenyl-1-[2-(tetrahydro-4-hydroxy-6-oxo-2H-pyran-2-yl)ethyl]-1H-pyrrole-3-carboxamide; *or* pharmaceutically acceptable salts thereof.
>
> 2. A compound of claim 1 which is [R-(R*,R*)]-2-(4-fluorophenyl)-β, σ-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)-carbonyl]-1H-pyrrole-1-heptanoic acid.
>
> * * *
>
> 6. *The hemicalcium salt of the compound of claim 2.*

DTX-35, col. 16, l. 60-col. 17, l. 12 (emphasis added).

The parties' claim construction dispute regarding claim 6 is whether claim 6 can be construed to cover the salt atorvastatin calcium. Ranbaxy contends that claim 6 cannot be construed to cover the salt, because claim 6 depends on claim 2 and claim 2 narrows the subject matter of claim 1 from atorvastatin acid or atorvastatin lactone, or pharmaceutically acceptable salts thereof to the single compound, atorvastatin acid. Ranbaxy argues that because claim 2 does not encompass salts, dependent claim 6 cannot cover the salt atorvastatin calcium. According to Ranbaxy, a reading of claim 6 to include the salt would render the patent invalid under Section 112, paragraph 4.

In response, Pfizer contends that Ranbaxy's claim construction is erroneous, because Ranbaxy incorrectly assumes that claim 6, a dependent claim, must incorporate all of the limitations of claim 2, from which it depends regardless of the actual language of claim 6. Because claim 6 expressly claims the hemicalcium salt of the compound of claim 2, Pfizer contends that claim 6 is properly construed to encompass the salt atorvastatin calcium.

The Court finds the language of claim 6 to be unambiguous to the extent that claim 6 is meant to claim the salt, atrovastatin calcium. The Court's conclusion is consistent with the express language of the claim and the understanding of the claim language to one skilled in the art. Claim 6 recites "[t]he hemicalcium salt of the compound of claim 2." Claim 2, on which claim 6 depends, defines atorvastatin acid. Thus, claim 6 effectively reads, "[t]he hemicalcium salt of atorvastatin acid." As a matter of standard chemical nomenclature, chemists typically refer to a salt of an acid, even though they are aware that the complete acid is technically no longer present in the salt form. Roush Tr. 910:3-912:4, 914:7-18. The specification of the '995 patent and claim 6 of the '995 patent comport with this standard practice by reciting the full name of the parent acid and then separately identifying the salt-forming ion. DTX-35, col. 4, ll. 3-6; Roush Tr. 914:7-18; Clive Tr. 1510:1-1517:2. Indeed, Ranbaxy utilizes this standard nomenclature in its ANDA application, as well. PTX-1011A at RA011211. Moreover, Ranbaxy's expert, Dr. Clive, had no difficulty understanding the language of claim 6 as referring to atorvastatin calcium. Clive Tr. 1507:7-1508:2; 1508:14-1509:24.

Despite this standard use of chemical nomenclature and the fact that the meaning of claim 6 is clear to those

skilled in the art, Ranbaxy contends that the Court should not interpret claim 6 to refer to atorvastatin calcium, because such an interpretation would render the claim invalid for failure to adhere to the drafting requirements for dependent claims set forth in Section 112. Pursuant to Section 112, paragraph 4, "a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed." Ranbaxy contends that there is a technical problem in the drafting of claim 6, because claim 1, from which claim 6 and claim 2 depend, recites three separate compositions: (1) atorvastatin acid; or (2) atorvastatin lactone; or (3) pharmaceutically acceptable salts of these two compounds. Claim 1 differentiates among these three compositions using the disjunctive "or." As a dependent claim, claim 2 narrows the subject matter of claim 1 from atorvastatin acid; or atorvastin lactone; or pharmaceutically acceptable salts thereof, to the single compound atorvastatin acid. If claim 2 is limited to atorvastatin acid and it excludes the limitation from claim 1 referring to "pharmaceutically acceptable salts thereof," then Ranbaxy argues that claim 6 cannot be read to encompass that which it expressly names, the hemicalcium salt of atorvastatin.

While the Court recognizes that there may be a technical problem in the drafting of claim 6, the question presented to the Court is whether this drafting problem is sufficient to render the claim invalid if the claim is read consistently with its meaning to those skilled in the art. To reach this conclusion, the Court would be required to declare an issued claim invalid because of the failure to

adhere to the drafting technicalities for dependent claims under Section 112, paragraph 4.[4] The Court has been unable to locate any precedent applying Section 112, paragraph 4 to invalidate a patent[5], and based on the legislative history of Section 112, paragraph 4, the Court understands the provision to be limited to matters of form,

---

[4] The Court is not persuaded that claim 6 can be read in any other manner, and Ranbaxy has not offered a plausible alternative reading for claim 6. Because the Court cannot construe the claim in any other manner, the question for the Court is whether claim 6 is invalid. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1328 (Fed. Cir. 2005) (reaffirming the principle that construing claims so as to maintain their validity is only applicable when the claim language is ambiguous and recognizing that claims cannot be construed differently from their plain meaning to uphold their validity); *Nazomi Communications, Inc. v. Arm Holdings, PLC*, 403 F.3d 1364, 1368-1371 (Fed. Cir. 2005) (stating that "courts should not rewrite claims to preserve validity"); *Rhine v. Casio, Inc.*, 183 F.3d 1342, 1345 (Fed. Cir. 1999) (recognizing that if "the only claim construction that is consistent with the claim's language and the written description renders the claim invalid," then "the claim is simply invalid").

[5] In arguing that Section 112, paragraph 4 should be considered an invalidating provision, Ranbaxy refers the Court to cases that applied Section 112, paragraph 1 to invalidate a patent for lack of written description and enablement and Section 112, paragraph 2 to invalidate a patent for indefiniteness. Ranbaxy contends that paragraph 4 should not be treated differently from paragraphs 1 and 2 of Section 112. The Court understands that the Federal Circuit has applied Section 112, paragraph 1 to invalidate a claim; however, the Court also understands that even this limited use of Section 112, paragraph 1 has not been embraced by all members of the Court. For example, there is significant disagreement over whether "written description" should be divorced from "enablement" and considered a separate and independent ground for invalidity. *See e.g. University of Rochester v. G.D. Searle & Co., Inc.*, 375 F.3d 1303, 1307-1314 (Fed. Cir. 2004) (Rader, J. dissenting and joined by Gajarsa, J. and Linn, J.); *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 976-987 (Fed. Cir. 2002) (Rader, J. dissenting and joined by Gajarsa, J. and Linn, J.). In light of this split among the Circuit judges, the Court is not persuaded that a further extension of invalidity principles to paragraph 4 should be made by this Court.

rather than matters of substance. Legislative history concerning this statutory section suggests that its provisions were meant to increase the fees payable to the Patent Office and expedite the prosecution of patent applications to make new technology available to the public more quickly. *See* S. Rep. No. 89-301 (1965), *reprinted in* 1965 U.S.C.C.A.N. 2315, 2319-2323. There is no indication in this legislative history that paragraph 4 was intended to be an invalidating provision. The Manual of Patent Examining Procedure ("MPEP") takes an approach consistent with the legislative history by viewing the failure to comply with paragraph 4 as a matter to be addressed through an objection to the claim and not a rejection of the claim's patentability under 35 U.S.C. § 112, 4.[6] Because the PTO considers improper dependent claims in this manner, the Court is not persuaded that the law of invalidity should be extended to reach Section 112, paragraph 4. Thus, the Court concludes that Section 112,

---

[6] MPEP 608.01(n) provides:

> Where a claim in dependent form is not considered to be a proper dependent claim under 37 C.F.R. 1.75(c), the examiner should object to such claim under 37 C.F.R. 1.75(c) and require cancellation of such improper dependent claim or rewriting of such improper dependent claim in independent form. See Ex parte Porter, 25 U.S.P.Q.2d 1144, 1147 (Bd. of Pat. App. & Inter. 1992) (A claim determined to be an improper dependent claim should be treated as a formal matter, in that the claim should be objected to and applicant should be required to cancel the claim (or replace the improper dependent claim with an independent claim) rather than treated by a rejection of the claim under 35 U.S.C. Section 112, fourth paragraph.). The applicant may thereupon amend the claims to place them in proper dependent form, or may redraft them as independent claims, upon payment of any necessary additional fee.

MPEP § 608.01(n) at 600-80 (8th ed. rev. 2, May 2004).

paragraph 4 should not be used to invalidate an issued patent claim.[7] *See* 35 U.S.C. § 282 (recognizing that issued patent has statutory presumption of validity); *Magnivision, Inc. v. Bonneau Co.*, 115 F.3d 956, 960 (Fed. Cir. 1997) ("Procedural lapses during examination, should they occur, do not provide grounds of invalidity. Absent proof of inequitable conduct, the examiner's or the applicant's absolute compliance with the internal rules of patent examination becomes irrelevant after the patent has issued.").

In sum, the Court interprets claim 6 of the patent to mean the salt of atorvastatin calcium. The Court's claim construction is consistent with the express language of the claim and the understanding of the claim to those skilled in the art. To the extent that the Court's claim construction conflicts with the requirements for dependent claims set forth in Section 112, paragraph 4, the Court concludes that this statutory provision provides no basis to invalidate a claim.

II. Infringement Of The '893 And '995 Patents

A. Applicable Legal Principles

A patent is infringed when a person "without authority makes, uses or sells any patented invention, within the United States during the term of the patent. . . ." 35 U.S.C. § 271(a). A patent owner may prove infringement under

---

[7] The Court further notes that the PTO raised no objections to the format or dependency of claim 6 or any of the other, similarly-worded claims to atovastatin salts, all of which depend on claim 2. DTX 139 at RA014772-74, RA014784, RA0147804-806, RA014813-14, RA014828-833.

either of two theories: literal infringement or the doctrine of equivalents. Literal infringement occurs where each element of at least one claim of the patent is found in the alleged infringer's product. *Panduit Corp. v. Dennison Mfg. Co.,* 836 F.2d 1329, 1330 n. 1 (Fed. Cir. 1987); Robert L. Harmon, *Patents and the Federal Circuit* 195 & n. 31 (3d ed.1994). In determining whether a patent has been literally infringed, the patent owner has the burden of proof and must meet its burden by a preponderance of the evidence. *SmithKline Diagnostics, Inc. v. Helena Lab. Corp.,* 859 F.2d 878, 889 (Fed. Cir. 1988) (citations omitted).

Infringement is a two step inquiry. Step one requires a court to construe the disputed terms of the patent at issue. Step two requires a court to compare the accused products with the properly construed claims of the patent. Having resolved the claim construction disputes regarding the '893 and '995 patents, the Court will proceed to a comparison between Ranbaxy's accused ANDA product and the claims of the '893 and '995 patents as construed by the Court.

B. Whether Pfizer Has Established By A Preponderance Of The Evidence That Ranbaxy's ANDA Product Literally Infringes The '893 Patent

The parties have stipulated that Ranbaxy's ANDA product contains the enantiomer atorvastatin calcium. Because the '893 patent has been construed to embrace enantiomers in the trans-form and not just racemates, the Court concludes that Ranbaxy's ANDA product literally infringes claims 1-4 of the '893 patent. The Court also concludes that Ranbaxy is likely to market or sell a composition containing atorvastatin calcium as embraced by

claim 8 of the '893 patent, for use in the method claimed by claim 9 of the '893 patent for inhibiting cholesterol biosynthesis in a patient in need of such treatment. Therefore, the Court concludes that Ranbaxy literally infringes claims 8 and 9 of the '893 patent.

C. Whether Pfizer Has Established By A Preponderance Of The Evidence That Ranbaxy's ANDA Product Literally Infringes The '995 Patent

Ranbaxy has admitted that the active ingredient, atorvastatin calcium, in Ranbaxy's ANDA product is the hemicalcium salt of the R-[R*, R*]-enantiomer. Because Ranbaxy's ANDA and associated Drug Master File ("DMF") indicate that its product will contain atorvastatin calcium, the Court concludes that Ranbaxy literally infringes claim 6 of the '995 patent as that claim has been interpreted by the Court.

III. The Validity Of The '893 Patent Term Extension

A. Applicable Legal Principles

Under the Hatch-Waxman Act, a patentee can obtain an extension of the ordinary patent term if the patent claims an invention which is subject to a regulatory review period before its commercial marketing or use. 35 U.S.C. § 156. Section 156 applies to a "drug product," which is defined, in pertinent part, as "a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Act), . . . including any salt or ester of the active ingredient as a single entity or in combination with another active ingredient." 35 U.S.C. § 156(f)(1), (2).

In applying for a patent extension, the applicant has a duty of candor and good faith toward the PTO, which encompasses a duty to disclose "material information adverse to a determination of entitlement to the extension sought, which has not been previously made of record in the patent term extension proceeding. . . ." 37 C.F.R. § 1.765(a). Information is considered material "where there is a substantial likelihood that the [PTO] . . . would consider it important in determinations to be made in the patent term extension proceeding." *Id.*

The presumption of validity applies to the PTO's determination to grant a patent term extension. To overcome this presumption, the party challenging the extension must come forward with clear and convincing evidence that the extension is invalid. *See Helfix Ltd. v. Blok-Lok Ltd.*, 208 F.3d 1339, 1346 (Fed. Cir. 2000).

B. Whether Ranbaxy Has Established By Clear And Convincing Evidence That The Patent Term Extension Of The '893 Is Invalid

Ranbaxy contends that the patent term extension of the '893 patent is invalid. Specifically, Ranbaxy contends that (1) the '893 patent does not claim atorvastatin calcium as required by 35 U.S.C. § 156; and (2) Pfizer violated the duty of disclosure by knowingly withholding from the Director representations made by Warner-Lambert regarding the '893 patent during the prosecution of the '995 patent and its European counterparts.

Based on the Court's claim construction of the '893 patent, the Court concludes that Ranbaxy's first argument provides no basis for invalidating the patent term extension of the '893 patent. The Court has construed the '893

patent to embrace atorvastatin calcium, and Pfizer provided the PTO with evidence supporting its assertion that the active pharmaceutical agent in Lipitor® is atorvastatin calcium. The PTO agreed with Pfizer's construction and concluded that the active ingredient in Lipitor® fell within the scope of the '893 patent. The PTO's determination in this regard is entitled to deference. *Merck & Co. v. Teva Pharms. U.S.A., Inc.*, 347 F.2d 1367, 1373-1374 (Fed. Cir. 2003) (citing *Glaxo Ops. UK Ltd. v. Quigg*, 894 F.2d 392, 399 (Fed. Cir. 1990)).

Ranbaxy contends that this case is similar to the circumstances in *Hoechst-Roussel Pharmaceuticals, Inc. v. Lehman*, 109 F.3d 756 (Fed. Cir. 1997).[8] In the Court's view, however, the circumstances in *Hoechst* are distinguishable from the circumstances in this case. In *Hoechst*, the Federal Circuit invalidated a patent term extension on the grounds that the patent did not claim the product at issue. The patent in *Hoechst* claimed the chemically distinct product 1-hydroxy-tacrine and the method of using that product. The patent did not claim the active ingredient of the product that received FDA approval, i.e. tacrine hydrochloride, or a method of using that ingredient. Rather, the active ingredient of the product at issue metabolized into the patented compound after it was

[8] Ranbaxy also relies on *Hoechst* to argue that the '893 patent does not "claim" atorvastatin calcium, because Ranbaxy contends that the patent lacks a sufficient written description to claim this compound under 35 U.S.C. § 112. Ranbaxy is correct that the Federal Circuit in *Hoechst* discussed the meaning of what a patent "claims" by reference to Section 112 for purposes of a patent term extension; however, the Court has previously concluded, in the context of its claim construction analysis, that the '893 patent is not invalid for lack of a written description.

ingested in the body. The Federal Circuit concluded that the active ingredient must be present in the drug product when administered for purposes of obtaining a valid patent term extension. Unlike *Hoechst,* in this case, the '893 patent claims the active ingredient in Lipitor®, and therefore, the Court concludes that *Hoechst* is inapposite.

Ranbaxy also contends that the patent term extension of the '893 patent is invalid based on Pfizer's alleged failure to disclose material information to the Director. In the context of its claim construction, the Court has concluded that the disclosures made by Warner-Lambert in connection with the prosecution of the '995 patent and foreign counterparts of the '893 patent are irrelevant to a determination of the scope of the claims of the '893 patent. Because this information is not relevant to the patent's scope, the Court concludes that Ranbaxy has not established that the allegedly withheld information is material such that it was required to be disclosed during the application process for the patent term extension. Accordingly, the Court concludes that Ranbaxy has not established that the patent term extension of the '893 patent is invalid.

IV. The Validity Of The '995 Patent

A. Whether Claim 6 Of The '995 Patent Is Invalid For Non-Statutory Double Patenting Over Pfizer's '080 Patent

1. Applicable Legal Principles

The non-statutory, obvious-type double patenting analysis involves two steps: (1) the court must construe the claim in the earlier patent and the later patent and determine the differences between the two patents, and (2) the court must determine whether the differences in the

subject matter between the two claims render the claims patentably distinct. *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001). In assessing the differences between the claims, the Court may not treat the earlier claim as prior art. Rather, specific attention must be given to what is claimed in the earlier patent. *General Foods Corp. v. Studiengesellschaft Kohle*, 972 F.2d 1272, 1278, 1280 (Fed. Cir. 1992) ("[I]t is important to bear in mind that comparison can be made only with what invention is *claimed* in the earlier patent, paying careful attention to the rules of claim interpretation to determine what invention a claim *defines* and not looking to the claim for anything that happens to be mentioned in it as though it were a prior art reference.") (italics in original). If the later claim is anticipated by or obvious in light of the earlier claim, then the later claim is not patentably distinct from the earlier claim, and it is invalid for obvious-type double patenting. *Barr*, 251 F.3d at 968.

Non-statutory double patenting is a judicially created doctrine, the purpose of which is to preclude a patent owner "from obtaining an extension of the right to exclude others from practicing his invention through claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent." *Id.* at 967-968; *see In re Lonardo*, 119 F.3d 960, 965 (Fed. Cir. 1997). Unlike the obviousness inquiry under 35 U.S.C. § 103, non-statutory double patenting does not require an inquiry into the objective criteria of non-obviousness. *Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1377-1378 n.1 (Fed. Cir. 2003).[9] The party challenging validity on the

[9] Pfizer contends that, notwithstanding Judge Rader's footnote in *Geneva*, it is appropriate to consider objective indicia of nonobviousness

(Continued on following page)

basis of non-statutory double patenting bears the burden of establishing invalidity by clear and convincing evidence. *Symbol Techs., Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1580 (Fed. Cir. 1991) (describing burden of proof for non-statutory double patenting as "heavy and unshifting").

2. Analysis

In this case, Ranbaxy asserts claims 12 and 14 of United States Patent No. 5,003,080 (the "'080 patent") as the earlier claims to be compared with claim 6 of the '995 patent. The '080 patent expires on March 26, 2008, prior to the expiration date of the '995 patent.

The Court has construed claim 6 of the '995 patent to refer to the specific compound, atorvastatin calcium. As such, claim 6 includes both the chemical structure and the properties of atorvastatin calcium.

Claim 12 of the '080 patent recites:

> A process for the preparation of the compound of Formula Ia [Formula Ia depiction] and the hydroxy acid and pharmaceutically acceptable salts thereof, corresponding to the opened lactone ring of the compound of Formula Ia which comprises:
>
> (a) reacting the compound of Formula XVII [depiction] with a compound of Formula [depiction] wherein R_7 and R_8 are independently hydrogen alkyl of from one to three carbon atoms,

---

in the case of nonstatutory, obvious-type double patenting. To the extent such an analysis of these secondary considerations is required, the Court incorporates by reference its discussion of these factors in the obviousness analysis contained in Section IV.B.2 *infra*.

> phenyl or R_7 and R_8 are taken together as $-(CH_2)_n$ wherein n is 4 or 5 and R_{13} is hydrogen or [depiction] in an inert solvent and treating the resulting intermediate with a 10% aqueas solution of hydrochloric acid to afford the compound of Formula Ia;
>
> (b) and if desired, converting the resulting compound of Formula Ia to a hydroxy acid corresponding to the opened lactone ring of structural Formula Ia by conventional hydrolysis and further, if desired, converting the hydroxy acid to a corresponding pharmaceutically acceptable salt by conventional means, and if so desired, converting the hydroxy acid to a compound of Formula Ia by heating in an inert solvent.

Construing claim 12 in light of the claim language and specification, the Court concludes that claim 12 refers to a process for preparing certain lactone compounds defined by Formula Ia and the opened-lactone ring hydroxy acids and pharmaceutically acceptable salts thereof. DTX-87, col. 56:46-58:24. Step (a) of this process reacts two intermediate compounds under certain identified conditions to provide Formula Ia lactone compounds. Pursuant to step (b), these lactones may then, be converted into a hydroxy acid by opening up the lactone ring. Once converted into a hydroxy acid, the hydroxy acid can then be converted into "pharmaceutically acceptable salts." The hydroxy acid can also be converted back to a lactone compound of Formula Ia, but step (b) does not include the conversion of the pharmaceutically acceptable salts back into the lactone compounds of Formula Ia.

Claim 14 of the '080 patent recites "A process according to claim 12 and for the preparation of (2R-trans)-5-(4-flourophenyl)-2-(1-methylethyl)-N, 4-diphenyl-1-[2-(tetrahydro-4-hydroxy-6-oxo-2H-pyran-2-yl)ethyl]-1H-pyrrole3-carboxamide." Based on the meaning of this express language to one skilled in the art, the Court construes claim 14 as referring to a process to produce the single compound, atorvastatin lactone.

Having construed the claims at issue, the Court must discern the differences among them and determine whether the subject matter of claim 6 is patentably distinct from the subject matter of claims 12 and 14 of the '080 patent. Claim 14 of the '080 patent claims a process for producing a single compound atorvastatin lactone. Neither this process nor this compound are contemplated by claim 6 of the '995 patent, and Ranbaxy has not demonstrated by clear and convincing evidence that claim 6 of the '995 patent recites an obvious variation of that which is recited in claim 14 of the '080 patent. *See Phillips Petroleum Co. v. U.S. Steel Corp.*, 673 F. Supp. 1278, 1311 (D. Del. 1987) (rejecting claim of double-patenting and concluding that no obvious variation existed where one patent claimed a process and the other claimed a product). The Court is persuaded that the inventions described in claim 14 of the '080 patent and claim 6 of the '995 patent are patentably distinct, and therefore, the Court concludes that claim 6 of the '995 patent is not invalid for non-statutory double patenting in light of claim 14 of the '080 patent.

As for claim 12 of the '080 patent, the Court likewise concludes that claim 12 presents an invention which is patentably distinct from that which is claimed in claim 6 of the '995 patent. Claim 12 of the '080 patent recites a

process capable of making a variety of compounds, while claim 6 of the '995 patent is directed to a single compound, atorvastatin calcium. Although the process described in claim 12 can be used to make atorvastatin calcium if the right starting products are selected, there is nothing in the '080 patent that would lead one to select the chemicals needed to produce the atorvastatin calcium claimed in the '995 patent. Roush Tr. 1902:11-1906:4. The Court is also not persuaded that one skilled in the art would have been led to select the necessary chemicals based on the state of the art at the time. When the '995 patent was filed, the only statin marketed was Lovastatin, which was in the lactone form, not the acid or salt form. In addition, if any salt was preferred at the time, it was the sodium salt form, not the calcium salt form. Roush Tr. 1862:15-1863:3; 1865:17-1866:2; Clive Tr. 1651:18-1655:21. In these circumstances, Ranbaxy has not established that one would be motivated to utilize claim 12 to make atorvastatin calcium, and therefore, the Court is not persuaded that claim 6 of the '995 patent is obvious over the '080 patent for purposes of the double-patenting analysis.

In addition, the Court concludes that claim 12 is appropriately characterized as a genus claim, because claim 12 of the '080 patent can yield a broad variety of compounds. In contrast, claim 6 of the '995 patent is appropriately characterized as a species claim, because it is directed to a single specific compound. Courts have recognized that later species claims are typically not invalidated in light of earlier genus claims on the basis of double patenting. *See e.g. In re Kaplan,* 789 F.2d 1574 (Fed. Cir. 1986) (reversing PTO's rejection of claim for double patenting and noting that double patenting does not necessarily arise because a broad or generic claim

reads on an invention defined by a narrower more specific claim in another patent); *In re Vogel,* 422 F.2d 438, 441 (C.C.P.A. 1970) (rejecting double patenting assertion against claims limited to pork based on earlier generic claim to meat).

Further, the invention claimed in the '080 patent has different uses and utilities than that which is claimed in the '995 patent. The utility of claim 12 of the '080 patent is based upon the advantages of the novel synthesis process described in the claim, DTX-87, col. 1, ll. 1-5, 39-50, 66-69, and the process claimed in the '080 patent can be practiced without infringing claim 6 of the '995 patent. In contrast, claim 6 of the '995 patent defines a compound, not a process, and that compound is claimed regardless of the process that is used to create it. *See Phillips Petroleum,* 673 F.Supp. at 1311. Stated another way, the compound recited in claim 6 does not depend for patentability on the method by which it is made. The compound is not a product-by-process claim, and it can be made without infringing the '080 patent by using a different production method. DTX-35; DTX-139. Indeed, the specification for the '995 patent discloses in its illustrations methods for making the compounds claimed in the patent which are different from the methods disclosed in the '080 patent. In addition, the utility of the '995 compound is its usefulness as an inhibitor of cholesterol biosynthesis for the treatment of hypercholesterolemia in humans. DTX-35, col. 1, ll. 18-19, 30-32, col. 2, ll. 39-53. The processes claimed in the '080 patent are not sold commercially for these purposes. In these circumstances, the Court cannot conclude that the compound recited in claim 6 of the '995 patent is an obvious variation of the process which is recited in claim 12 of the '080 patent.

Ranbaxy directs the Court to the Federal Circuit's decision in *Eli Lilly & Co. v. Barr Laboratories, Inc.*, 251 F.3d 955 (Fed. Cir. 2001), for the proposition that a later claim to fluoxetine hydrochloride salt was invalid for non-statutory double patenting as anticipated by an earlier claim to pharmaceutically acceptable salts. In the Court's view, however, Ranbaxy misstates the basis for the *Barr* Court's conclusion of double patenting. In *Barr,* the Federal Circuit considered claim 1 of the '213 patent, which was directed to a method for treating anxiety in a human by administering an effective amount of fluoxetine or a pharmaceutically acceptable salt thereof. This claim was compared with claim 7 of the '549 patent which claimed a method of blocking the uptake of serotonin by brain neurons in animals by administering the compound fluoxetine hydrochloride. In considering these claims, the Federal Circuit stated that "[a] person of ordinary skill in the art would have recognized that fluoxetine hydrochloride is a pharmaceutically-acceptable salt of fluoxetine;" however, the claim was not invalid for double patenting on that basis. Rather, the Federal Circuit went on to recognize that the serotonin intake described in claim 7 of the '549 patent is precisely what happens in the treatment of anxiety, and thus, there was no patentable distinction between that which was claimed in claim 1 of the '213 patent and that which was claimed in claim 7 of the '549 patent.[10]

---

[10] The Federal Circuit also recognized that the earlier claim was directed to a specific species, humans, while the later claim was directed to a genus, animals. The Federal Circuit stated that "[o]ur case law firmly establishes that a later genus claim limitation is anticipated by, and therefore not patentably distinct from, an earlier species claim." *Barr,* 251 F.3d at 971. As the Court has noted, however, this case

(Continued on following page)

The circumstances in this case differ from the circumstances in *Barr,* and therefore, the Court is not persuaded that the *Barr* case dictates the results here. Because the Court has concluded that distinct differences exist between claims 12 and 14 of the '080 patent and claim 6 of the '995 rendering them patentably distinct, the Court concludes that Ranbaxy has not established invalidity of claim 6 of the '995 patent on the grounds of non-statutory double patenting.

B. Whether Claim 6 Of The '995 Patent Is Obvious In Light Of The '893 Patent

1. Applicable Legal Principles

In pertinent part, 35 U.S.C. § 103 provides that a patent may not be obtained "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious to a person having ordinary skill in the art . . . " 35 U.S.C. § 103. Obviousness is a question of law which is predicated upon several factual inquiries. *Richardson-Vicks v. Upjohn Co.,* 122 F.3d 1476, 1479 (Fed. Cir. 1997). Specifically, in determining whether a patent is invalid as obvious over the prior art, the trier of fact must consider (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed subject matter and the prior art; and (4) secondary considerations of non-obviousness, such as commercial success, long felt but unsolved need, failure of others,

---

presents the converse situation, i.e. a genus claim followed by a species claim, a scenario which does not raise anticipation problems and which is typically permissible. *See In re Kaplan,* 789 F.2d 1574.

and acquiescence of others in the industry that the patent is valid. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). The party challenging validity on the grounds of obviousness must establish that the patents are invalid by clear and convincing evidence. *C.R. Bard, Inc. v. M3 Sys.*, 157 F.3d 1340, 1351 (Fed. Cir. 1998).

2. Analysis

Ranbaxy asserts the '893 patent as the relevant prior art to be considered in the analysis of whether the '995 patent is obvious. The '893 patent was cited and relied upon during the prosecution of the '995 patent. DTX 139 at RA014773-774, 779-781, 789-790, 805-806, 813-816, 829-832.

With respect to the level of ordinary skill in the art pertaining to the '995 patent, the parties essentially agree that one skilled in the art would have at least a Bachelor's degree in organic or medicinal chemistry, a general knowledge of statins, several years of bench work in organic molecule synthesis and some general knowledge of biochemistry and enzymology. The parties also agree that one skilled in the art would have knowledge pertaining to the stereochemistry of pharmaceutically active ingredients and the resolving of racemates. Roush Tr. 1773:22-1774:14; 1786:12-1788:4; Scallen Tr. 1112:10-14. Ranbaxy asserted at trial that one skilled in the art would have a Ph.D., but Ranbaxy contends that this educational difference is immaterial to the obviousness analysis. To the extent the Court is required to make a finding on this disputed issue, the Court finds that one skilled in the art is not necessarily required to have a Ph.D. in light of the skill and knowledge base one can obtain through the work experience identified by

the parties as essential to the level of ordinary skill in the relevant art.

Having identified the level of skill in the art and the relevant prior art, the Court must next consider the differences between the prior art and the claimed subject matter, as well as the objective indicia of non-obviousness. In conducting this analysis, the Court also considers whether one skilled in the art would have been motivated to modify the '893 patent to reconstruct atorvastatin calcium.

Unlike the '995 patent which is specifically directed to the calcium salt of atorvastatin, the '893 patent does not specifically name, exemplify or depict a specific calcium salt. Rather, the '893 patent broadly includes calcium among at least 50 possible salts, and mentions no preference for calcium as compared with the other possible salts. DTX 13, col. 7, ll. 1-17; Clive Tr. 1581:6-1583:17; Roush Tr. 1860:1-1862:14. Indeed, if any salt was preferred at the time among the more than fifty to one hundred available, the evidence indicates that it would have been sodium salt. Clive Tr. 1651:18-1655:6; Roush Tr. 1862:15-1865:16; PTX 2058, col. 5, first paragraph. Further, the art at the time suggests that the selection of salts is a difficult task. Given the unique properties each salt imparts to the parent compound, salt selection is not a routine process and the success of a given salt is not easily predicted. DTX-3081; Roush Tr. 1865:17-1871:16; Clive Tr. 1524:1-1536:10. In these circumstances, the Court finds that, at best, it would have been obvious for medicinal chemists to try various salts in an attempt to find a salt with properties suitable for pharmaceutical use. However, "obvious to try" does not equate with obviousness for purposes of Section 103. *See e.g. In re Deuel,* 51 F.3d 1552, 1559 (Fed.

Cir. 1995) ("'Obvious to try' has long been held not to constitute obviousness."). Accordingly, the Court is not persuaded that one skilled in the art would have been motivated to select calcium, or that one could have a reasonable expectation that the selection of calcium would be successful.

Ranbaxy also contends that it would have been obvious to one skilled in the art to obtain atorvastatin calcium from the racemates of atorvastatin disclosed in the '893 patent. The Court disagrees with Ranbaxy's position. Although the '893 patent identifies racemic atorvastatin lactone as compound 1, there is nothing in the '893 patent expressing a preference for that compound as opposed to the thousands of other individual compounds identified by the '893 patent. Moreover, the Court is not persuaded that one skilled in the art during the relevant time period would have selected compound 1 as a starting point for the ultimate separation of that compound into its individual enantiomers. First, the prior art indicates that the motivation at the time was to develop racemates and make structural changes to the compounds to increase their activity, not to resolve those racemates into individual isomers. The resolution of racemates into their individual isomers yielded, at best, an expectation of a two-fold increase in activity. This modest increase in activity was offset by the difficulty and complexity of the resolution process, as well as the reduced yield and increased waste disposal problems. Roush Tr. 1807:15-1813:20, 1820:16-1830:4, 1831:14-1837:3; PTX 2058, 2064, 2681, 2694. Further, the Court is persuaded by Dr. Roush's testimony, that if there was a motivation to resolve the racemates, a medicinal chemist attempting to improve the activity of the compounds in the '893 patent would begin

with the most active compound identified in the patent, compound 3. As Dr. Roush explained, expectations at the time would have led a medicinal chemist to expect no more than a two-fold increase in activity from racemic compound 1, which is the same activity level as compound 3 before compound 3 was separated into its component enantiomers. Roush Tr. 1838:18-1845:5, 1846:8-1847:14, 1853:13-1854:15, 2018:6-2022:4. As a result, the Court cannot conclude that there was any motivation in the prior art or reasonable expectation of success that would lead one skilled in the art to resolve compound 1 into its individual enantiomers.

In addition to the differences between the prior art and claim 6 of the '995 patent and the lack of motivation to resolve compound 1 described in the '893 patent into its individual enantiomers, the Court also concludes that objective indicia of non-obviousness support the validity of claim 6 of the '995 patent. Prior to the filing date of the '995 patent, no commercial statin had been marketed in the form of a calcium salt. Roush Tr. 1871:6-11. Lipitor®, which contains as its active pharmaceutical agent the compound recited in claim 6 of the '995 patent, was the first such product and its commercial and medical success, though unexpected, has been well-documented. Susserman Tr. 810:2-814:20; Bokhart Tr. 2350:13-19, 2374:4-2375:19. Ranbaxy contends that Lipitor®,s success is the result of Pfizer's marketing strategies and not the efficacy of the product; however, Pfizer has produced several studies and clinical trials which demonstrate the benefits derived from the use of atorvastatin calcium and its superiority over other compounds. *See e.g.* PTX-337, 336, 351, 354, 347, 366, 2007; Jones Tr. 1711:24-1717:27; Sasiela Tr. 2450:14-2451:9, 2460:1-2462:4. In the Court's view, this

evidence is sufficient to demonstrate that Lipitor®,s success was the result of its medical efficacy compared with other products.

To this effect, the Court also finds that Lipitor® satisfied a long-felt need in the medical community to provide patients with more effective statins to help them achieve their LDL goals. Sasiela Tr. 2417:20-2419:3; Susserman Tr. 795:2-20; Bowman Tr. 2578:4-2581:10; Jones Tr. 1696:6-1699:16; PTX 349. Despite the efforts of others to make effective statins, Lipitor® proved to be more successful than those products available on the market at the time. Indeed, the fact that Ranbaxy has chosen to copy Lipitor® in its ANDA further demonstrates the success and efficacy of Lipitor® compared with other available products.

In sum, the Court concludes that Ranbaxy has not demonstrated that claim 6 of the '995 patent is obvious in light of the '893 patent. The '893 patent claims a genus of compounds, while the '995 patent claims a species of that genus. There was no motivation in the prior art to select the species compound of atorvastatin calcium from the genus of compounds identified in the '893 patent, and absent such a motivation, the Court cannot conclude that the '893 genus patent renders the '995 species patent obvious. In addition, the Court concludes that indicia of non-obviousness support the validity of the '995 patent. Accordingly, the Court concludes that Ranbaxy has not demonstrated by clear and convincing evidence that claim 6 of the '995 patent is obvious.

C. Whether Claim 6 Of The '995 Patent Is Anticipated By The '893 Patent

1. Applicable Legal Principles

The party challenging validity on the basis of anticipation under 35 U.S.C. § 102(g), must show that the potentially invalidating patent or invention (1) qualifies as prior art; (2) was not abandoned, suppressed or concealed; and (3) is identical to the claimed invention or process. To show identicality between prior art and the claimed invention, the party challenging validity must show that each and every step or element of the claimed process or invention is disclosed in a single prior art reference or embodied in a single prior art device or practice, either expressly or inherently. *Hazani v. United States Int'l Trade Comm'n,* 125 F.3d 1473, 1477 (Fed. Cir. 1997). "[I]nvalidity by anticipation requires that the four corners of a single, prior art document describe every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation." *Advanced Display Sys., Inc. v. Kent State Univ.,* 212 F.3d 1272, 1282 (Fed. Cir. 2000).

2. Analysis

Ranbaxy contends that claim 6 of the '995 patent is anticipated by the '893 patent. Specifically, Ranbaxy contends that the '893 patent discloses atorvastatin lactone and the hydroxy acid and pharmaceutically acceptable salts derived from the lactone. Ranbaxy also points out that the '893 patent discloses calcium as one of the seven listed pharmaceutically acceptable salts.

In response, Pfizer contends that the prior art disclosure of a racemate does not anticipate either of its individual isomers. Pfizer also contends that the earlier disclosure of a genus does not anticipate an undisclosed species member of the genus.

The Federal Circuit has recognized that the "earlier disclosure of a genus does not necessarily prevent patenting a species member of that genus." *Eli Lilly & Co. v. Bd. of Regents of the Univ. of Washington,* 334 F.3d 1264, 1270 (citing *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.,* 246 F.3d 1368, 1380 (Fed. Cir. 2001)). Although the '893 patent mentions calcium as one of the seven listed pharmaceutically acceptable salts, the '893 patent does not expressly identify atorvastatin calcium, the species compound claimed in the '995 patent. In the Court's view, an approach to the '893 patent which interprets this passing reference to calcium as an anticipation of the later claimed compound atorvastatin calcium is the type of "mechanistic dissection and recombination" that results in a finding of anticipation by hindsight. *See In re Ruschig,* 343 F.2d 965, 974 (C.C.P.A. 1965) (disavowing "the mechanistic dissection and recombination of the components of the specific illustrative compounds in every chemical reference containing them, to create hindsight anticipations with the guidance of an applicant's disclosures, on the theory that such reconstructed disclosures describe specific compounds within the meaning of section 102"). Further, courts considering issues related to racemates and their individual isomers have concluded that a prior art disclosure of a racemate does not anticipate the individual isomers of the racemate or render the individual isomers of the racemate obvious. *See In re May,* 574 F.2d 1082 (C.C.P.A. 1978) (holding that "the novelty of an optical

isomer is not negated by the prior art disclosure of its racemate"); *Ortho-McNeil Pharms., Inc. v. Myland Labs., Inc.*, 348 F. Supp. 2d 713, 720-721, 761-764 (N.D.W. Va. 2004) (discussing patentability of an optically active isomer (enantiomer) over prior art and use in commerce of its racemic mixture); *see also Eli Lilly v. Generix Drug Sales, Inc.*, 460 F.2d 1096, 1104 (5th Cir. 1972) (noting that individual d-isomer was the "repository of the useful and novel invention claimed" and affirming infringement of claim limited in words to a racemic mixture). Accordingly, the Court concludes that Ranbaxy has not established that the species compound claimed in the '995 patent is anticipated by the genus of compounds claimed in the '893 patent.

V. The Enforceability Of The '995 Patent Due To Inequitable Conduct

A. Applicable Legal Principles

Patent applicants and their patent attorneys have a duty of candor, good faith and honesty in their dealings with the PTO. 37 C.F.R. § 1.56(a). The duty of candor, good faith and honesty includes the duty to submit truthful information and the duty to disclose to the PTO information known to the patent applicants or their attorneys which is material to the examination of the patent application. *Elk Corp. of Dallas v. GAF Bldg. Materials Corp.*, 168 F.3d 28, 30 (Fed. Cir. 1999). Breach of the duty of candor, good faith and honesty may constitute inequitable conduct. *Id.* If it is established that a patent applicant engaged in inequitable conduct before the PTO, the entire patent application so procured is rendered unenforceable. *Kingsdown Med. Consultants v. Hollister Inc.*, 863 F.2d 867, 877 (Fed. Cir. 1988).

To establish inequitable conduct due to the failure to disclose material information or the submission of false information, the party raising the issue must prove by clear and convincing evidence that (1) the information is material; (2) the knowledge of this information and its materiality is chargeable to the patent applicant; and (3) the applicant's submission of false information or its failure to disclose this information resulted from an intent to mislead the PTO. *Id.* Information is deemed material if there is a substantial likelihood that a reasonable examiner would have considered the material important in deciding whether to issue the application as a patent. *See Elk Corp.,* 168 F.3d at 31; *Mobil Oil Corp. v. Advanced Envtl. Recycling Techs., Inc.,* 869 F. Supp. 251, 254 (D. Del. 1994). Accordingly, a reference does not have to be prior art to be material information that must be disclosed to the PTO. *See* 37 C.F.R. § 1.56; *Mobil Oil Corp.,* 869 F. Supp. at 255. Further, "an otherwise material reference need not be disclosed if it is merely cumulative of or less material than other references already disclosed." *Elk Corp.,* 168 F.3d at 31.

Intent to deceive is rarely established by direct evidence, and therefore, may be inferred from the facts and circumstances surrounding the applicant's overall conduct. *See Molins PLC v. Textron, Inc.,* 48 F.3d 1172, 1180 (Fed. Cir. 1995). In determining whether the applicant's overall conduct evidences an intent to deceive the PTO, the Federal Circuit has emphasized that the challenged "conduct must be sufficient to require a finding of deceitful intent in the light of all the circumstances." *Kingsdown Med. Consultants,* 863 F.2d at 873. Once materiality and intent have been established, the court must conduct a balancing test to determine "whether the scales tilt to a

conclusion that 'inequitable conduct' occurred." *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997). Generally, the more material the omission, the less the degree of intent that must be shown to reach a conclusion of inequitable conduct. *Elk Corp.*, 168 F.3d at 32.

The question of whether inequitable conduct occurred is equitable in nature. As such, the ultimate question of whether inequitable conduct occurred is committed to the sound discretion of the trial court. *Elk Corp.*, 168 F.3d at 30-31; *Kingsdown Med. Consultants*, 863 F.2d at 876.

B. Whether Warner-Lambert Engaged In Equitable Conduct During The Prosecution Of The '995 Patent

Ranbaxy contends that, during the prosecution of the '995 patent, Warner-Lambert withheld material information concerning other patents in their portfolio and misrepresented the cholesterol inhibition activity of the compounds at issue. Specifically, Ranbaxy contends that the '080 patent filed in February 1988 and its CIP application filed in February 1989 were not disclosed to the PTO, but both of these references give rise to prima facie unpatentability of the '995 patent based on obvious-type double patenting. Ranbaxy also contends that Warner-Lambert withheld results from *in vivo* experiments called AICS screens ("AICS data") and results from *in vitro* experiments called CSI screens ("CSI data") which demonstrated no significant difference in activity of the material compounds. Ranbaxy contends that this information was contrary to the representations made by Warner-Lambert, through Dr. Roth and Dr. Daignault, that its compound had "activity at least ten-fold more than that of the racemate," and therefore,

showed "surprising and unexpected results" because the activity of the R isomer would only be expected to be twice that of the racemic mixture. As a result of the failure to disclose this information, Ranbaxy contends that Warner-Lambert intentionally deceived the PTO as to the patentability of the '995 invention.

In response, Pfizer contends that Ranbaxy cannot establish intent to deceive the PTO. Pfizer contends that Dr. Roth dealt with two separate attorneys for the '080 patent and the '995 patent, and that he never considered whether the '080 patent should have been brought to the attention of the '995 patent examiner, because the patents involved what Dr. Roth considered to be two very different inventions. Pfizer also contends that Dr. Daignault had limited involvement in the '995 patent prosecution and that while he signed papers for the '080 patent, he did not do significant substantive work on it. As a result, Pfizer contends that Dr. Daignault was not knowledgeable in the '080 patent, and therefore, he had no deliberate intent to withhold it from the PTO.

As for the AICS and CSI data, Pfizer contends that Ranbaxy's allegations of inequitable conduct based on the alleged withholding of data are hindsight reconstructions that fail to take into account the "real world" conditions under which Dr. Roth discovered Lipitor®. Pfizer contends that Dr. Roth had no intent to deceive the PTO and that the data identified by Ranbaxy is not material.

1. The '080 patent and the CIP application for the '080 patent

Reviewing the record as it relates to the '080 patent and the CIP application for the '080 patent, the Court

concludes that Ranbaxy has not established that Dr. Daignault or Dr. Roth intentionally deceived the PTO by failing to disclose these references. Although Dr. Daignault signed the application papers for the '080 patent as the attorney of record, Dr. Tinney was responsible for the substantive preparation of the application. DTX-88 at RA014464-465; Daignault Tr. 1267:20-1269:6; Tinney Tr. 2225:18-2227:5. At the time, Dr. Tinney could not sign the papers, because he had not yet passed the patent bar. Prosecution of the '080 patent was abandoned in favor of the expanded CIP application. The expanded CIP application, and not the original '080 application contains the express disclosure of enantiomers upon which Ranbaxy relies.

By the time the '080 CIP application was ready for filing, Dr. Tinney had his PTO registration. As a result, Dr. Tinney, prepared and prosecuted the '080 CIP application. Dr. Daignault had no involvement in the CIP, and Dr. Tinney and Dr. Daignault both testified that they did not discuss the '080 CIP application with each other. Daignault Tr. 1269:22-1271:4, 1271:12-1272:14; Tinney Tr. 2237:16-2239:9; 2231:6-17.

The '995 patent application was prepared and prosecuted by a different Warner-Lambert attorney, Joan Theirstein. Dr. Tinney had no involvement in the '995 prosecution, and Dr. Tinney and Ms. Theirstein never discussed the '080 issued patent or CIP application with each other. DTX-139; Tinney Tr. 2240:1-24; Theirstein Dep. Tr. 91:14-92:22. In December 1991, Ms. Theirstein left Warner-Lambert suddenly and Dr. Daignault was required to assume the prosecution of the '995 patent on short notice. Daignault Tr. 1260:10-1262:12, 1263:4-24; Theirstein Dep. Tr. 110:13-15. Dr. Daignault filed and

argued the appeal of the anticipation rejection to the PTO Board of Appeals and signed the issue fee transmittal to the PTO in early September 1993. Daignault Tr. 1263:14-20; 1264:3-5; 1265:6-17; 1266:16-1267:19; 1273:11-1274:11; DTX 139 at RA014808-809. Dr. Daignault testified that he was not consciously aware of the '080 CIP application at the time he prosecuted the '995 appeal in December 1991, which was approximately two years after his involvement with the '080 patent. Daignault Tr. 1271:12-1272:5; 1274:12-1275:10; 1314:24-1315:24. Dr. Daignault also testified that he never considered citing the '080 patent during the '995 appeal period or thereafter. Dr. Daignault was responsible for more than 150 ongoing active patent prosecutions in addition to his administrative duties at the time. Daignault Tr. 1272:6-14. Dr. Daignault's involvement with the '080 patent and the CIP application were limited and the duties he assumed with regard to the '995 patent were likewise limited in nature. In these circumstances, the Court cannot conclude that Dr. Daignault's failure to consciously consider the '080 patent or the CIP was the result of any intent to deceive the PTO.

With respect to Dr. Roth, the evidence adduced at trial demonstrates that Dr. Roth dealt with two separate attorneys during the '080 and '995 patent prosecutions. Roth Tr. 305:10-24. Dr. Roth testified that he never considered whether the '080 patent or CIP application should have been brought to the attention of the patent examiner. Roth Tr. 306:1-12. In this regard, Dr. Roth testified that he considered the patents to involve two different processes. Roth Tr. 305:1-12, 306:1-12. In these circumstances, the Court cannot conclude that Dr. Roth's views were based on any intent to deceive the PTO. Accordingly, the Court is

not persuaded that Dr. Roth acted intentionally to withhold the '080 patent from the PTO.

2. The AICS data

Ranbaxy contends that Dr. Roth intentionally withheld *in vivo* rat data generated in an AICS screen from the PTO during the prosecution of the '995 patent. This data was contained in a May 1989 research report in which the author, a biologist named Dr. Krause, concluded that the R-isomer was "approximately twofold more active at inhibiting cholesterol synthesis acutely *in vivo*" compared to racemic atorvastatin. DTX-11. Ranbaxy contends that this material was intentionally withheld from the PTO, because it contradicted other data provided by Warner-Lambert to support its assertion that the R-isomer was ten times more active than the racemate.

Reviewing the testimony and evidence adduced at trial in light of the applicable legal standards, the Court concludes that Ranbaxy has not demonstrated by clear and convincing evidence that the *in vivo* rat data was material or intentionally withheld by Dr. Roth. AICS *in vivo* assays are not used to measure the absolute or intrinsic inhibitory activity of a compound. Particularly, the fact that these assays are conducted *in vivo,* in a live animal, presents a variety of complicating factors that make these studies unreliable for determining whether a given compound is having a direct effect on the inhibition of cholesterol synthesis. Roth Tr. 169:5-8, 170:17-171:6; 293:13-295:1. Instead, *in vitro* data is the best and most relevant data for comparing the absolute or intrinsic activity of compounds to inhibit cholesterol biosynthesis. Roth Tr. 178:13-187:6, 261:20-263:5. Accordingly, the Court

cannot conclude that Ranbaxy has established, by clear and convincing evidence, that this data was material.

In addition, the Court cannot conclude that Dr. Roth intentionally withheld this data from the PTO with the intent to deceive. Dr. Roth testified that he believed *in vivo* data could not be used to measure the intrinsic inhibitory activity of a compound, because it was influenced by a number of factors such as metabolism and absorption in the body. Roth Tr. 293:13-295:1. Indeed, Dr. Roth did not use AICS data to make quantitative comparisons of the activity of compounds or in developing his SAR or QSAR theories which led to the discovery of atorvastatin calcium. Roth Tr. 292:20-294:7. Thus, the Court finds that the evidence demonstrates that Dr. Roth made a good faith determination that the AICS data was not relevant.[11] Roth Tr. 291:19-294:7, 343:1-344:6, 364:11-19.

Ranbaxy argues that the AICS data was submitted to the FDA when Warner-Lambert sought approval for Lipitor®, and therefore, it must have been material data. However, a determination of materiality before the PTO is not governed by that which is required for submission to the FDA. *See Ortho-McNeil Pharm.,* 2004 WL 2973831 at *23-24. Ranbaxy refers the Court to the Federal Circuit's decision in *Bruno Independent Living Aids, Inc. v. Acorn Mobility Services, Ltd.,* 394 F.3d 1348 (Fed. Cir. 2005) to

---

[11] *See e.g. Hoffmann-LaRoche, Inc. v. Promega Corp.,* 323 F.3d 1354, 1361 (Fed. Cir. 2003) (reversing finding of intent to deceive where evidence showed that inventors, in good faith, did not believe results of experiment were relevant); *Allied Colloids Inc. v. American Cyanamid Co.,* 64 F.3d 1570, 1578 (Fed. Cir. 1995) ("It is not inequitable conduct to omit telling the patent examiner information that the applicant in good faith believes is not material to patentability.").

support its argument that material submitted to the FDA should have been disclosed to the PTO and the failure to do so demonstrates an intent to deceive. In the Court's view, however, the *Bruno* case is distinguishable from the circumstances here. In *Bruno,* the Federal Circuit rejected the patentee's assertion that certain representations made to the FDA about prior art were only relevant to securing FDA approval and had no bearing on whether the patentee knew those references were material prior art for purposes of patentability. In reaching this conclusion, the Federal Circuit highlighted the fact that the FDA submission was prepared by the same individual who was involved in the prosecution of the patent-in-suit and that individual had asked an attorney to conduct a prior art search in preparation for the filing of the patent application. *Id.* at 1352. Unlike *Bruno,* the FDA submission in this case does not involve prior art but the submission of data, which the Court has already concluded was withheld based on the credible assertion that the data was unreliable. Further, Dr. Roth was not involved in the FDA submissions, and therefore, the FDA submissions cannot be used to infer that Dr. Roth believed the AICS data was material to patentability. Roth Tr. 332:23-24. Accordingly, the Court cannot conclude that Ranbaxy has established by clear and convincing evidence that Dr. Roth intentionally withheld material data from the PTO with the intent to deceive the PTO as to the inhibitory activity of atorvastatin calcium.

3. The CSI data

Ranbaxy also contends that Warner-Lambert intentionally withheld certain CSI data and manipulated the CSI data that was disclosed to deceive the PTO and

support its assertions concerning the activity of atorvastatin calcium. Ranbaxy contends that like the AICS data discussed above, the withheld CSI data showed the comparative activity between the R-isomer and the racemic compound to be far lower than the "ten times" difference asserted by Warner-Lambert. Ranbaxy contends that this data was material to patentability and not cumulative, and therefore, Warner-Lambert had a duty to disclose it.

The biological data contained in the '995 patent specification were generated from an *in vitro* assay called CSI. The CSI assay measures the absolute or inherent activity of compounds to inhibit cholesterol biosynthesis. The data for the sodium salt of the R-isomer and S-isomer are from the same experiment, CSI test 120, the most recent CSI experiment available to Dr. Roth at the time. The data collected for racemic atorvastatin sodium salt represents an average of five separate assays.

Ranbaxy contends that the use of this average number was misleading and demonstrates an intent to deceive the PTO. The Court concludes there was no intent to deceive. The experts agree that head-to-head testing provides the best way to compare quantitative differences in activity. Roth Tr. 264:22-265:18; Scallen Tr. 1133:3-6. Dr. Roth initially located a head-to-head comparison for the sodium salts of the R-isomer and S-isomer, but the sodium racemate was not included in that experiment. Dr. Roth did what he considered to be the next best thing, which was to collect all of the then-available data for the racemate and calculate the historical average. Roth Tr. 264:22-272:16; PTX 2538 at P0236600. When asked to check for additional data, Dr. Roth then found a single head-to-head comparison with all three forms of calcium salt in CSI-118. Roth Tr. 265:21-267:9, 273:1-276:5. This data was submitted to the

PTO in Dr Roth's declaration. Roth Tr. 273:5-275:19, 279:11-15; PTX 2538 at P0236601-602; PTX 2055.

Ranbaxy also points to other data which Dr. Roth allegedly concealed, including the atorvastatin lactone value from CSI-107, the racemic sodium salt value from CSI 118 and the racemic calcium salt data from CSI 119. The Court finds that this evidence is insufficient to establish clearly and convincingly that this data was withheld to intentionally deceive the PTO. Dr. Roth has alleged credible and good faith reasons for his failure to include certain data in his reports. For example, the atorvastatin compounds tested in CSI-107 were based on Warner-Lambert's first crude attempt to resolve racemic atorvastatin. Roth Tr. 252:3-253:5; PTX 283 at P0250205. The results were impure R-trans and S-trans isomers that were contaminated with their opposite isomer. Dr. Roth did not know what effect this contamination would have on the biological activity of the R-isomer, so he relied on comparisons using pure isomers. Roth Tr. 265:19-266:11, 397:18-398:22; DTX 3323.

As for Ranbaxy's assertion that the racemic sodium value from CSI-118 should have been disclosed along with the calcium values, Dr. Roth explained that it is inappropriate to compare across salts, because different salts have different solubilities. Thus, Dr. Roth believed that it was only appropriate to compare the same salts within an experiment. Roth Tr. 263:16-265:18, 414:24-415:21, 419:5-420:5. Along a similar vein, Dr. Roth did not provide the data from CSI-119, because he believed it was inappropriate to compare individual data points from different experiments. CSI 119 was not a head-to-head comparison, and was not a repeat of CSI 118. Moreover, the CSI 119 experiment showed a worse than normal solubility problem

noted as "chunks," a problem which was not noted in the CSI 118 experiment[12], which was fully disclosed in Dr. Roth's declaration and is the only CSI experiment where all three calcium salts of racemic atorvastatin and the R-isomer and the S-isomer were tested head-to-head. In the Court's view, sound reasons support Dr. Roth's decision not to submit certain CSI data to the PTO, and therefore, the Court cannot conclude that Ranbaxy has demonstrated that Dr. Roth intended to deceive the PTO by withholding certain CSI data.

4. Summary

In sum, the Court concludes that Ranbaxy has not established by clear and convincing evidence that the '995 patent was procured through inequitable conduct. Although the '080 patent was not revealed during the prosecution of the '995 patent, the Court is not persuaded that it was intentionally withheld. The circumstances related to the drafting and prosecution of the '080 and '995 patents, including the workload of Dr. Daignault and his limited roles in each of the patents, suggest that Dr. Daignault was not dishonest in his claim that he did not consider the '080 patent during the prosecution of the '995 patent. Similarly, the Court cannot conclude that Dr. Roth was dishonest in his view that the '080 patent and '995 patents referred to two separate inventions.

---

[12] The technician noted that the calcium salt compounds in CSI 118 were "insoluble," but there was no notation regarding chunks. As Dr. Dietschy explained the statins as a whole have poor solubility, but solutions with "gross lumps" are the worse scenario and are "unacceptable . . . to begin with." Dietschy Tr. 2116:6-2117:17, 2124:4-2129:11, 2205:24-2207:19; PTX 2115-2118.

As for the data submission issue, the Court is not persuaded that Warner-Lambert manipulated or "cherry picked" data with deceitful motives to achieve a deceitful result. Pfizer had ample data to support the claims it made to the PTO, and it provided the PTO with the data it believed was scientifically sound. The Court is not persuaded that the instances of non-disclosure cited by Ranbaxy are sufficient to demonstrate an intent to deceive the PTO. Pfizer has advanced reasonable and credible grounds for the non-production of certain data that weigh against a conclusion that Warner-Lambert scientists and employees were intentionally deceiving the PTO. Because Ranbaxy has not met its burden of establishing inequitable conduct, the Court will enter judgment in favor of Pfizer and against Ranbaxy on Ranbaxy's counterclaim that the '995 patent is unenforceable as a result of inequitable conduct.

CONCLUSION

For the reasons discussed, the Court concludes that Pfizer has established that Ranbaxy's ANDA product literally infringes the '893 and '995 patents, and therefore, the Court will enter judgment in favor of Pfizer and against Ranbaxy on Pfizer's claims of infringement. In addition, the Court concludes that Ranbaxy has not established that the '893 patent is invalid under 35 U.S.C. § 112, ¶ 1, or that the patent term extension of the '893 patent is invalid, and therefore, the Court will enter judgment in favor of Pfizer and against Ranbaxy on Ranbaxy's counterclaims of invalidity of the '893 patent and invalidity of the patent term extension. With respect to the '995 patent, the Court further concludes that Ranbaxy has not established unenforceability as a result of

inequitable conduct or invalidity based on double patenting, obviousness and anticipation, and therefore, the Court will enter judgment in favor of Pfizer and against Ranbaxy on Ranbaxy's counter claims of invalidity and unenforceability of the '995 patent.

Pfizer shall submit, with notice to Ranbaxy, a proposed Final Judgment Order by December 23, 2005.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC, PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, WARNER-LAMBERT COMPANY, LLC and WARNER-LAMBERT EXPORT, LTD.,	)	
Plaintiffs,	)	**C.A. No. 03-209-JJF (Consolidated)**
v.	)	
RANBAXY LABORATORIES LIMITED, and RANBAXY PHARMACEUTICALS INCORPORATED,	)	
Defendants.	)	

FINAL JUDGMENT ORDER

This action having come to trial before the Court, Honorable Joseph J. Farnan, Jr., District Judge presiding; the issues having been heard and a decision having been rendered:

IT IS ORDERED AND ADJUDGED this 3rd day of January, 2006, for the reasons set forth in the Court's Memorandum Opinion dated December 16, 2005, that Judgment shall be entered in favor of plaintiffs Pfizer Inc, Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, Warner-Lambert Company LLC and Warner-Lambert Export, Ltd. (collectively "Pfizer") and against defendants Ranbaxy Laboratories Limited and Ranbaxy Pharmaceuticals Incorporated (collectively "Ranbaxy") on

Pfizer's claims that Ranbaxy has infringed claims 1-4, and 8-9 of United States Patent No. 4,681,893 (the "'893 Patent") and claim 6 of United States Patent No. 5,273,995 (the "'995 Patent"); and it is further,

ORDERED AND ADJUDGED that Judgment shall be entered in favor of Pfizer and against Ranbaxy on all counterclaims alleging noninfringement, invalidity, or unenforceability of the '893 Patent or its patent term extension; and it is further,

ORDERED AND ADJUDGED that Judgment shall be entered in favor of Pfizer and against Ranbaxy on all counterclaims alleging noninfringement, invalidity, or unenforceability of the '995 Patent; and it is further,

ORDERED that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Ranbaxy's Abbreviated New Drug Application No. 76-477 shall be a date which is not earlier than the date of expiration of the '893 Patent and its patent term extension (September 24, 2009, with attached six months of pediatric exclusivity ending on March 24, 2010, to which Pfizer is entitled); and it is further,

ORDERED that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Ranbaxy's Abbreviated New Drug Application No. 76-477 shall be a date which is not earlier than the date of expiration of the '995 Patent (December 28, 2010, with attached six months of pediatric exclusivity ending on June 28, 2011, to which Pfizer is entitled); and it is further,

ORDERED that pursuant to 35 U.S.C. § 271(e)(4)(B), defendants Ranbaxy Laboratories Limited and Ranbaxy Pharmaceuticals Incorporated, each of their officers,

agents, servants, employees and attorneys, and those persons in active concert or participation with them or either of them are permanently enjoined from engaging in the manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any product comprising atorvastatin calcium covered by, or the use of which is covered by claims 1-4 and 8-9 of the '893 Patent; and it is further,

ORDERED that pursuant to 35 U.S.C. § 271(e)(4)(B), defendants Ranbaxy Laboratories Limited and Ranbaxy Pharmaceuticals Incorporated, each of their officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them or either of them are permanently enjoined from engaging in the manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any product comprising atorvastatin calcium covered by, or the use of which is covered by claim 6 of the '995 Patent.

/s/ Joseph J. Farnan Jr.
United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, WARNER-LAMBERT COMPANY, LLC, and WARNER-LAMBERT EXPORT, LTD.,	:	
Plaintiffs,	:	Civil Action No. 03-209-JJF
v.	:	(Consolidated)
RANBAXY LABORATORIES LIMITED and RANBAXY PHARMACEUTICALS, INC.,	:	
Defendants.	:	

ORDER

WHEREAS, the Court of Appeals for the Federal Circuit has issued its decision in the above-captioned appeal, affirming-in-part, reversing-in-part, and remanding this matter for modification of the permanent injunction; *Pfizer Inc. v. Ranbaxy Laboratories Ltd.*, 457 F.3d 1284 (Fed. Cir. 2006);

WHEREAS, specifically, the Federal Circuit concluded that United States Patent No. 5,273,995 (the "'995 patent") was invalid for failure to comply with the requirements of 35 U.S.C. § 112, ¶ 4;

NOW THEREFORE, IT IS HEREBY ORDERED that, consistent with the Federal Circuit's decision, the last paragraph of the Final Judgment Order dated January 3, 2006, and entered by the Court on January 4, 2006,

enjoining Defendants and others "from engaging in the manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any product comprising atorvastatin calcium covered by, or the use of which is covered by claim 6 of the '995 Patent" is ***STRICKEN***.

November 7, 2006
DATE

/s/ Joseph J. Farnan Jr.
UNITED STATES
DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, WARNER-LAMBERT COMPANY, LLC, and WARNER-LAMBERT EXPORT, LTD.,	:	
Plaintiffs,	:	Civil Action No. 03-209-JJF
v.	:	(Consolidated)
RANBAXY LABORATORIES LIMITED and RANBAXY PHARMACEUTICALS, INC.,	:	
Defendants.	:	

ORDER

WHEREAS, by Order dated November 7, 2006, the Court modified the Final Judgment Order entered on January 4, 2006, in light of the decision by the Court of Appeals for the Federal Circuit that United States Patent No. 5,273,995 (the "'995 patent) is invalid;

WHEREAS, it has come to the Court's attention that further modification of the Final Judgment Order is required;

WHEREAS, because the '995 patent has been declared invalid, a basis no longer exists to support delaying the approval of Ranbaxy's Abbreviated New Drug Application No. 76-477 ("ANDA");

NOW THEREFORE, IT IS FURTHER ORDERED that the sixth paragraph of the Final Judgment Order

delaying the effective date of any approval of Ranbaxy's ANDA until a date not earlier than the expiration of the '995 patent is ***STRICKEN***.

November 30, 2006
DATE

/s/ Joseph J. Farnan Jr.
UNITED STATES
DISTRICT JUDGE

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

06-1179

PFIZER INC., PFIZER IRELAND PHARMACEUTICALS,
WARNER-LAMBERT COMPANY,
WARNER-LAMBERT COMPANY, LLC and
WARNER-LAMBERT EXPORT, LTD.,

Plaintiffs-Appellees,

v.

RANBAXY LABORATORIES LIMITED and
RANBAXY PHARMACEUTICALS INCORPORATED,

Defendants-Appellants.

ORDER

(Filed Oct. 23, 2006)

A combined petition for panel rehearing and for rehearing en banc having been filed by the Appellants and a response thereto having been invited by the court and filed by the Appellees, and the petition for rehearing and response, having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc and response having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on October 30, 2006.

FOR THE COURT,

/s/ Jan Horbaly/JB
Jan Horbaly
Clerk

Dated: 10/23/2006

cc: Darrell L. Olson
Rudolf E. Hutz

PFIZER INC V RANBAXY LABS, 2006-1179
(DCT-03-CV-209)

United States Court of Appeals for the Federal Circuit

06-1179

PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, WARNER-LAMBERT COMPANY, LLC and WARNER-LAMBERT EXPORT, LTD.,

Plaintiffs-Appellees,

v.

RANBAXY LABORATORIES LIMITED and RANBAXY PHARMACEUTICALS INCORPORATED,

Defendants-Appellants.

Judgment

ON APPEAL from the UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

In CASE NO(S). 03-CV-209

This CAUSE having been heard and considered, it is

ORDERED and ADJUDGED:

AFFIRMED-IN-PART, REVERSED-IN-PART and REMANDED.

ENTERED BY ORDER OF THE COURT

DATED AUG -2 2006

/s/ Jan Horbaly/Lms
Jan Horbaly, Clerk

ISSUED AS A MANDATE: OCT 30 2006

35 U.S.C. § 156 Extension of patent term

(a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment granted under section 154(b), if –

(1) the term of the patent has not expired before an application is submitted under subsection (d)(1) for its extension;

(2) the term of the patent has never been extended under subsection (e)(1) of this section;

(3) an application for extension is submitted by the owner of record of the patent or its agent and in accordance with the requirements of paragraphs (1) through (4) of subsection (d);

(4) the product has been subject to a regulatory review period before its commercial marketing or use;

(5) (A) except as provided in subparagraph (B) or (C), the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred;

(B) in the case of a patent which claims a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of a

product manufactured under the process claimed in the patent; or

(C) for purposes of subparagraph (A), in the case of a patent which –

(i) claims a new animal drug or a veterinary biological product which (I) is not covered by the claims in any other patent which has been extended, and (II) has received permission for the commercial marketing or use in non-food-producing animals and in food-producing animals, and

(ii) was not extended on the basis of the regulatory review period for use in non-food-producing animals,

the permission for the commercial marketing or use of the drug or product after the regulatory review period for use in food-producing animals is the first permitted commercial marketing or use of the drug or product for administration to a food-producing animal.

The product referred to in paragraphs (4) and (5) is hereinafter in this section referred to as the "approved product".

(b) Except as provided in subsection (d)(5)(F), the rights derived from any patent the term of which is extended under this section shall during the period during which the term of the patent is extended –

(1) in the case of a patent which claims a product, be limited to any use approved for the product –

(A) before the expiration of the term of the patent –

(i) under the provision of law under which the applicable regulatory review occurred, or

(ii) under the provision of law under which any regulatory review described in paragraph (1), (4), or (5) of subsection (g) occurred, and

(B) on or after the expiration of the regulatory review period upon which the extension of the patent was based;

(2) in the case of a patent which claims a method of using a product, be limited to any use claimed by the patent and approved for the product –

(A) before the expiration of the term of the patent –

(i) under any provision of law under which an applicable regulatory review occurred, and

(ii) under the provision of law under which any regulatory review described in paragraph (1), (4), or (5) of subsection (g) occurred, and

(B) on or after the expiration of the regulatory review period upon which the extension of the patent was based; and

(3) in the case of a patent which claims a method of manufacturing a product, be limited to the method of manufacturing as used to make –

(A) the approved product, or

(B) the product if it has been subject to a regulatory review period described in paragraph (1), (4), or (5) of subsection (g).

As used in this subsection, the term "product" includes an approved product.

(c) The term of a patent eligible for extension under subsection (a) shall be extended by the time equal to the regulatory review period for the approved product which period occurs after the date the patent is issued, except that –

(1) each period of the regulatory review period shall be reduced by any period determined under subsection (d)(2)(B) during which the applicant for the patent extension did not act with due diligence during such period of the regulatory review period;

(2) after any reduction required by paragraph (1), the period of extension shall include only one-half of the time remaining in the periods described in paragraphs (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g);

(3) if the period remaining in the term of a patent after the date of the approval of the approved product under the provision of law under which such regulatory review occurred when added to the regulatory review period as revised under paragraphs (1) and (2) exceeds fourteen years, the period of extension shall be reduced so that the total of both such periods does not exceed fourteen years; and

(4) in no event shall more than one patent be extended under subsection (e)(1) for the same regulatory review period for any product.

(d) (1) To obtain an extension of the term of a patent under this section, the owner of record of the patent or its agent shall submit an application to the Director. Except as provided in paragraph (5), such an application may only be submitted within the sixty-day period beginning on the date the product received

permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use. The application shall contain –

(A) the identity of the approved product and the Federal statute under which regulatory review occurred;

(B) the identity of the patent for which an extension is being sought and the identity of each claim of such patent which claims the approved product or a method of using or manufacturing the approved product;

(C) information to enable the Director to determine under subsections (a) and (b) the eligibility of a patent for extension and the rights that will be derived from the extension and information to enable the Director and the Secretary of Health and Human Services or the Secretary of Agriculture to determine the period of the extension under subsection (g);

(D) a brief description of the activities undertaken by the applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities; and

(E) such patent or other information as the Director may require.

(2) (A) Within 60 days of the submittal of an application for extension of the term of a patent under paragraph (1), the Director shall notify –

(i) the Secretary of Agriculture if the patent claims a drug product or a method of using or manufacturing a drug product and

the drug product is subject to the Virus-Serum-Toxin Act, and

(ii) the Secretary of Health and Human Services if the patent claims any other drug product, a medical device, or a food additive or color additive or a method of using or manufacturing such a product, device, or additive and if the product, device, and additive are subject to the Federal Food, Drug, and Cosmetic Act,

of the extension application and shall submit to the Secretary who is so notified a copy of the application. Not later than 30 days after the receipt of an application from the Director, the Secretary receiving the application shall review the dates contained in the application pursuant to paragraph (1)(C) and determine the applicable regulatory review period, shall notify the Director of the determination, and shall publish in the Federal Register a notice of such determination.

(B) (i) If a petition is submitted to the Secretary making the determination under subparagraph (A), not later than 180 days after the publication of the determination under subparagraph (A), upon which it may reasonably be determined that the applicant did not act with due diligence during the applicable regulatory review period, the Secretary making the determination shall, in accordance with regulations promulgated by such Secretary, determine if the applicant acted with due diligence during the applicable regulatory review period. The Secretary making the determination shall make such determination not later than 90 days after the receipt of such a petition. For a drug

product, device, or additive subject to the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act, the Secretary may not delegate the authority to make the determination prescribed by this clause to an office below the Office of the Director of Food and Drugs. For a product subject to the Virus-Serum-Toxin Act, the Secretary of Agriculture may not delegate the authority to make the determination prescribed by this clause to an office below the Office of the Assistant Secretary for Marketing and Inspection Services.

(ii) The Secretary making a determination under clause (i) shall notify the Director of the determination and shall publish in the Federal Register a notice of such determination together with the factual and legal basis for such determination. Any interested person may request, within the 60-day period beginning on the publication of a determination, the Secretary making the determination to hold an informal hearing on the determination. If such a request is made within such period, such Secretary shall hold such hearing not later than 30 days after the date of the request, or at the request of the person making the request, not later than 60 days after such date. The Secretary who is holding the hearing shall provide notice of the hearing to the owner of the patent involved and to any interested person and provide the owner and any interested person an opportunity to participate in the hearing. Within 30 days after the completion of the hearing, such Secretary shall affirm or revise the determination

which was the subject of the hearing and shall notify the Director of any revision of the determination and shall publish any such revision in the Federal Register.

(3) For the purposes of paragraph (2)(B), the term "due diligence" means that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period.

(4) An application for the extension of the term of a patent is subject to the disclosure requirements prescribed by the Director.

(5) (A) If the owner of record of the patent or its agent reasonably expects that the applicable regulatory review period described in paragraph (1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii) of subsection (g) that began for a product that is the subject of such patent may extend beyond the expiration of the patent term in effect, the owner or its agent may submit an application to the Director for an interim extension during the period beginning 6 months, and ending 15 days, before such term is due to expire. The application shall contain –

(i) the identity of the product subject to regulatory review and the Federal statute under which such review is occurring;

(ii) the identity of the patent for which interim extension is being sought and the identity of each claim of such patent which claims the product under regulatory review or a method of using or manufacturing the product;

(iii) information to enable the Director to determine under subsection (a)(1), (2) and (3) the eligibility of a patent for extension;

(iv) a brief description of the activities undertaken by the applicant during the applicable regulatory review period to date with respect to the product under review and the significant dates applicable to such activities; and

(v) such patent or other information as the Director may require.

(B) If the Director determines that, except for permission to market or use the product commercially, the patent would be eligible for an extension of the patent term under this section, the Director shall publish in the Federal Register a notice of such determination, including the identity of the product under regulatory review, and shall issue to the applicant a certificate of interim extension for a period of not more than 1 year.

(C) The owner of record of a patent, or its agent, for which an interim extension has been granted under subparagraph (B), may apply for not more than 4 subsequent interim extensions under this paragraph, except that, in the case of a patent subject to subsection (g)(6)(C), the owner of record of the patent, or its agent, may apply for only 1 subsequent interim extension under this paragraph. Each such subsequent application shall be made during the period beginning 60 days before, and ending 30 days before, the expiration of the preceding interim extension.

(D) Each certificate of interim extension under this paragraph shall be recorded in the official

file of the patent and shall be considered part of the original patent.

(E) Any interim extension granted under this paragraph shall terminate at the end of the 60-day period beginning on the date on which the product involved receives permission for commercial marketing or use, except that, if within that 60-day period the applicant notifies the Director of such permission and submits any additional information under paragraph (1) of this subsection not previously contained in the application for interim extension, the patent shall be further extended, in accordance with the provisions of this section –

(i) for not to exceed 5 years from the date of expiration of the original patent term; or

(ii) if the patent is subject to subsection (g)(6)(C), from the date on which the product involved receives approval for commercial marketing or use.

(F) The rights derived from any patent the term of which is extended under this paragraph shall, during the period of interim extension –

(i) in the case of a patent which claims a product, be limited to any use then under regulatory review;

(ii) in the case of a patent which claims a method of using a product, be limited to any use claimed by the patent then under regulatory review; and

(iii) in the case of a patent which claims a method of manufacturing a product, be limited to the method of manufacturing as used to make the product then under regulatory review.

(e) (1) A determination that a patent is eligible for extension may be made by the Director solely on the basis of the representations contained in the application for the extension. If the Director determines that a patent is eligible for extension under subsection (a) and that the requirements of paragraphs (1) through (4) of subsection (d) have been complied with, the Director shall issue to the applicant for the extension of the term of the patent a certificate of extension, under seal, for the period prescribed by subsection (c). Such certificate shall be recorded in the official file of the patent and shall be considered as part of the original patent.

(2) If the term of a patent for which an application has been submitted under subsection (d)(1) would expire before a certificate of extension is issued or denied under paragraph (1) respecting the application, the Director shall extend, until such determination is made, the term of the patent for periods of up to one year if he determines that the patent is eligible for extension.

(f) For purposes of this section:

(1) The term "product" means:

(A) A drug product.

(B) Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.

(2) The term "drug product" means the active ingredient of –

(A) a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act), or

(B) a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Virus-Serum-Toxin Act) which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques,

including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

(3) The term "major health or environmental effects test" means a test which is reasonably related to the evaluation of the health or environmental effects of a product, which requires at least six months to conduct, and the data from which is submitted to receive permission for commercial marketing or use. Periods of analysis or evaluation of test results are not to be included in determining if the conduct of a test required at least six months.

(4) (A) Any reference to section 351 is a reference to section 351 of the Public Health Service Act.

(B) Any reference to section 503, 505, 512, or 515 is a reference to section 503, 505, 512, or 515 of the Federal Food, Drug, and Cosmetic Act.

(C) Any reference to the Virus-Serum-Toxin Act is a reference to the Act of March 4, 1913 (21 U.S.C. 151-158).

(5) The term "informal hearing" has the meaning prescribed for such term by section 201(y) of the Federal Food, Drug, and Cosmetic Act.

(6) The term "patent" means a patent issued by the United States Patent and Trademark Office.

(7) The term "date of enactment" as used in this section means September 24, 1984, for a human drug product, a medical device, food additive, or color additive.

(8) The term "date of enactment" as used in this section means the date of enactment of the Generic Animal Drug and Patent Term Restoration Act for an animal drug or a veterinary biological product.

(g) For purposes of this section, the term "regulatory review period" has the following meanings:

(1) (A) In the case of a product which is a new drug, antibiotic drug, or human biological product, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory review period for a new drug, antibiotic drug, or human biological product is the sum of –

(i) the period beginning on the date an exemption under subsection (i) of section 505 or subsection (d) of section 507 became effective for the approved product and ending on the date an application was initially submitted for such drug product under section 351, 505, or 507, and

(ii) the period beginning on the date the application was initially submitted for the

approved product under section 351, subsection (b) of section 505, or section 507 and ending on the date such application was approved under such section.

(2) (A) In the case of a product which is a food additive or color additive, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory review period for a food or color additive is the sum of –

(i) the period beginning on the date a major health or environmental effects test on the additive was initiated and ending on the date a petition was initially submitted with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product, and

(ii) the period beginning on the date a petition was initially submitted with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product, and ending on the date such regulation became effective or, if objections were filed to such regulation, ending on the date such objections were resolved and commercial marketing was permitted or, if commercial marketing was permitted and later revoked pending further proceedings as a result of such objections, ending on the date such proceedings were finally resolved and commercial marketing was permitted.

(3) (A) In the case of a product which is a medical device, the term means the period described in

subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory review period for a medical device is the sum of –

(i) the period beginning on the date a clinical investigation on humans involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515, and

(ii) the period beginning on the date an application was initially submitted with respect to the device under section 515 and ending on the date such application was approved under such Act or the period beginning on the date a notice of completion of a product development protocol was initially submitted under section 515(f)(5) and ending on the date the protocol was declared completed under section 515(f)(6).

(4) (A) In the case of a product which is a new animal drug, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory review period for a new animal drug product is the sum of –

(i) the period beginning on the earlier of the date a major health or environmental effects test on the drug was initiated or the date an exemption under subsection (j) of section 512 became effective for the approved new animal drug product and ending on the date an application was initially submitted for such animal drug product under section 512, and

(ii) the period beginning on the date the application was initially submitted for the approved animal drug product under subsection (b) of section 512 and ending on the date such application was approved under such section.

(5) (A) In the case of a product which is a veterinary biological product, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory period for a veterinary biological product is the sum of –

(i) the period beginning on the date the authority to prepare an experimental biological product under the Virus-Serum-Toxin Act became effective and ending on the date an application for a license was submitted under the Virus-Serum-Toxin Act, and

(ii) the period beginning on the date an application for a license was initially submitted for approval under the Virus-Serum-Toxin Act and ending on the date such license was issued.

(6) A period determined under any of the preceding paragraphs is subject to the following limitations:

(A) If the patent involved was issued after the date of the enactment of this section, the period of extension determined on the basis of the regulatory review period determined under any such paragraph may not exceed five years.

(B) If the patent involved was issued before the date of the enactment of this section and –

(i) no request for an exemption described in paragraph (1)(B) or (4)(B) was submitted

and no request for the authority described in paragraph (5)(B) was submitted,

(ii) no major health or environmental effects test described in paragraph (2)(B) or (4)(B) was initiated and no petition for a regulation or application for registration described in such paragraph was submitted, or

(iii) no clinical investigation described in paragraph (3) was begun or product development, protocol described in such paragraph was submitted,

before such date for the approved product the period of extension determined on the basis of the regulatory review period determined under any such paragraph may not exceed five years.

(C) If the patent involved was issued before the date of the enactment of this section and if an action described in subparagraph (B) was taken before the date of the enactment of this section with respect to the approved product and the commercial marketing or use of the product has not been approved before such date, the period of extension determined on the basis of the regulatory review period determined under such paragraph may not exceed two years or in the case of an approved product which is a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act or the Virus-Serum-Toxin Act), three years.

(h) The Director may establish such fees as the Director determines appropriate to cover the costs to the Office of receiving and acting upon applications under this section.

(Sept. 24, 1984, Pub. L., 98-417, §201, 98 Stat. 1598-1602; Nov. 16, 1988, Pub. L. 100-670, §201, 102 Stat. 3984-3988;

Dec. 3, 1993, Pub. L. 103-179, §§5-6, 107 Stat. 2040; Dec. 8, 1994, Pub. L. 103-465, §532, 108 Stat. 4983; Nov. 21, 1997, Pub. L. 105-115, §125, 111 Stat. 2326; Nov. 29, 1999, Pub. L. 106-113, §4404, 113 Stat. 1501A-560; Nov. 2, 2002, Pub. L. 107-273, §13206, 116 Stat. 1904.)

35 U.S.C. § 282 Presumption of validity; defenses

A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. Notwithstanding the preceding sentence, if a claim to a composition of matter is held invalid and that claim was the basis of a determination of nonobviousness under section 103(b)(1), the process shall no longer be considered nonobvious solely on the basis of section 103(b)(1). The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.

The following shall be defenses in any action involving the validity or infringement of a patent and shall be pleaded:

(1) Noninfringement, absence of liability for infringement or unenforceability,

(2) Invalidity of the patent or any claim in suit on any ground specified in part II of this title as a condition for patentability,

(3) Invalidity of the patent or any claim in suit for failure to comply with any requirement of sections 112 or 251 of this title,

(4) Any other fact or act made a defense by this title.

In actions involving the validity or infringement of a patent the party asserting invalidity or noninfringement shall give notice in the pleadings or otherwise in writing to the adverse party at least thirty days before the trial, of the country, number, date, and name of the patentee of any patent, the title, date, and page numbers of any

publication to be relied upon as anticipation of the patent in suit or, except in actions in the United States Claims Court,* as showing the state of the art, and the name and address of any person who may be relied upon as the prior inventor or as having prior knowledge of or as having previously used or offered for sale the invention of the patent in suit. In the absence of such notice proof of the said matters may not be made at the trial except on such terms as the court requires.

Invalidity of the extension of a patent term or any portion thereof under section 154(b) or 156 of this title because of the material failure –

(1) by the applicant for the extension, or

(2) by the Director,

to comply with the requirements of such section shall be a defense in any action involving the infringement of a patent during the period of the extension of its term and shall be pleaded. A due diligence determination under section 156(d)(2) is not subject to review in such an action.

(July 19, 1952, ch. 950, §1, 66 Stat. 812; July 24, 1965, Pub. L. 89-83, §10, 79 Stat. 261; Nov. 14, 1975, Pub. L. 94-131, §10, 89 Stat. 692; Apr. 2, 1982, Pub. L. 97-164, §161, 96 Stat. 49; Sept. 24, 1984, Pub. L. 98-417, §203, 98 Stat. 1603; Nov. 1, 1995, Pub. L. 104-41, §2, 109 Stat. 352; Nov. 29, 1999, Pub. L. 106-113, §4402, 113 Stat. 1501A-557.)

---

* *Ed. Note*: Pursuant to the Court of Federal Claims Technical and Procedural Improvements Act of 1992, §902(b)(2), Pub. L. 102-572, 106 Stat. 4516, statutory references to the U.S. Claims Court are deemed to refer to the U.S. Court of Federal Claims.

37 C.F.R. § 1.765 Duty of disclosure in patent term extension proceedings.

(a) A duty of candor and good faith toward the Patent and Trademark Office and the Secretary of Health and Human Services or the Secretary of Agriculture rests on the patent owner or its agent, on each attorney or agent who represents the patent owner and on every other individual who is substantively involved on behalf of the patent owner in a patent term extension proceeding. All such individuals who are aware, or become aware, of material information adverse to a determination of entitlement to the extension sought, which has not been previously made of record in the patent term extension proceeding must bring such information to the attention of the Office or the Secretary, as appropriate, in accordance with paragraph (b) of this section, as soon as it is practical to do so after the individual becomes aware of the information. Information is material where there is a substantial likelihood that the Office or the Secretary would consider it important in determinations to be made in the patent term extension proceeding.

(b) Disclosures pursuant to this section must be accompanied by a copy of each written document which is being disclosed. The disclosure must be made to the Office or the Secretary, as appropriate, unless the disclosure is material to determinations to be made by both the Office and the Secretary, in which case duplicate copies, certified as such, must be filed in the Office and with the Secretary. Disclosures pursuant to this section may be made to the Office or the Secretary, as appropriate, through an attorney or agent having responsibility on behalf of the patent owner or its agent for the patent term extension proceeding or through a patent owner acting on his or her own behalf.

Disclosure to such an attorney, agent or patent owner shall satisfy the duty of any other individual. Such an attorney, agent or patent owner has no duty to transmit information which is not material to the determination of entitlement to the extension sought.

(c) No patent will be determined eligible for extension and no extension will be issued if it is determined that fraud on the Office or the Secretary was practiced or attempted or the duty of disclosure was violated through bad faith or gross negligence in connection with the patent term extension proceeding. If it is established by clear and convincing evidence that any fraud was practiced or attempted on the Office or the Secretary in connection with the patent term extension proceeding or that there was any violation of the duty of disclosure through bad faith or gross negligence in connection with the patent term extension proceeding, a final determination will be made pursuant to § 1.750 that the patent is not eligible for extension.

(d) The duty of disclosure pursuant to this section rests on the individuals identified in paragraph (a) of this section and no submission on behalf of third parties, in the form of protests or otherwise, will be considered by the Office. Any such submissions by third parties to the Office will be returned to the party making the submission, or otherwise disposed of, without consideration by the Office.

[24 FR 10332, Dec. 22, 1959, as amended at 54 FR 30381, July 20, 1989; 60 FR 25618, May 12, 1995]